

## 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-10011328705	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Dizziness (0d - Recovered/Resolved - ), Fatigue (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011328782	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (1d - Recovered/Resolved - ), Dizziness (0d - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ), Injection site pain (2d - Recovering/Resolving - ), Limb discomfort (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011329337	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Diarrhoea (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011330809	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Fatigue (0d - Recovering/Resolving - ), Injection site pain (1d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011330934	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ), Limb discomfort (0d - Unknown - ), Lymphadenopathy (1d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011330984	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Dizziness (1d - Not Recovered/Not Resolved - ), Headache (0d - Recovered/Resolved - ), Limb discomfort (1d - Not Recovered/Not Resolved - ), Nausea (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011330986	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (n/a - Unknown - ), Fatigue (1d - Unknown - ), Feeling hot (n/a - Unknown - ), Headache (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>

										Nausea (n/a - Unknown - )			
EU-EC-10011331748	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Paraesthesia (n/a - Recovering/Resolving - ), Visual impairment (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011332500	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Abdominal pain (n/a - Recovered/Resolved - ), Crying (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Recovered/Resolved - ), Rash (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011335840	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Asthenia (2d - Recovered/Resolved - ), Crying (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011309004	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Crying (21d - Recovering/Resolving - ), Fatigue (21d - Recovering/Resolving - ), Headache (21d - Recovering/Resolving - ), Initial insomnia (21d - Recovering/Resolving - ), Maternal exposure during breast feeding (21d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011309150	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Poor weight gain neonatal (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Thymus enlargement (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011309924	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Unknown - ), Headache (2d - Unknown - ), Nausea (2d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011309933	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Arthralgia (1d - Recovering/Resolving - ), Asthenia (1d - Recovering/Resolving - ), Headache (1d - Recovering/Resolving - ), Maternal exposure during breast feeding (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>

										Middle insomnia (1d - Recovering/Resolving - ), Myalgia (1d - Recovering/Resolving - ), Productive cough (1d - Recovering/Resolving - ), Screaming (1d - Recovering/Resolving - )			
EU-EC-10011310598	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Recovered/Resolved - Disabling), Vomiting (n/a - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011311404	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[TOPIRAMATE] (C - n/a - Unknown - [n/a - 15mg - n/a]), [VIGABATRIN] (C - n/a - Unknown - [n/a - 300mg - n/a])	<a href="#">ICSR</a>
EU-EC-10011314567	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Rash (97d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011317064	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Agitation (1d - Recovered/Resolved - ), Crying (1d - Recovered/Resolved - ), Vomiting projectile (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011293128	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Dizziness (15min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011298334	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Arrhythmia neonatal (n/a - Recovering/Resolving - Life Threatening), Atrial fibrillation (n/a - Recovering/Resolving - Life Threatening), Cardiac failure (n/a - Recovering/Resolving - Life Threatening), Cardiogenic shock (n/a - Recovering/Resolving - Life Threatening), Cardiovascular disorder (n/a - Recovering/Resolving - Life Threatening), Foetal exposure during pregnancy (n/a - Recovering/Resolving - Life Threatening), Neonatal asphyxia (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011301096	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<a href="#">ICSR</a>

										Maternal exposure during breast feeding (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting projectile (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	applicable - [n/a - n/a]		
EU-EC-10011301322	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Disabling), Flatulence (n/a - Recovering/Resolving - Disabling), Maternal exposure during breast feeding (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011302687	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Regurgitation (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Oral])	Not reported	<a href="#">ICSR</a>
EU-EC-10011305530	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (3d - Recovered/Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Eye swelling (0d - Recovered/Resolved - ), Lacrimation increased (0d - Not Recovered/Not Resolved - ), Mood altered (3d - Recovered/Resolved - ), Rash erythematous (0d - Recovered/Resolved - ), Rhinoorrhoea (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011305576	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011285508	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Crying (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [90d - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011288504	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain upper (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Malaise (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011278184	15/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Not Specified	Male	No	Poor feeding infant (n/a - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not	Not reported	<a href="#">ICSR</a>

						- 2 Years					Recovered/Resolved (-)  applicable - [n/a - n/a - Intramuscular]),  COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]),  SPIKEVAX [COVID- 19 MRNA VACCINE MODERNA (CX- 024414)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])			
EU-EC- 10011263826	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Cloacal exstrophy (n/a - Not Recovered/Not Resolved - Life Threatening, Congenital Anomaly),  Exposure during pregnancy (n/a - Not Recovered/Not Resolved - Life Threatening, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10011267321	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Feeling hot (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Hyperaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Hypoesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Slow response to stimuli (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Visual impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	

EU-EC-10011275888	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Recovered/Resolved - Caused/Prolonged Hospitalisation) Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Skin discolouration (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	[ALUMINIUM, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, 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, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, 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, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS,	<a href="#">ICSR</a>
-------------------	------------	-------------	-------------------------	------------------------	---------------	--------------------	--------	------	----	--	---	---	----------------------

POLIOMYELITIS  
VIRUS  
(INACTIVATED)  
TYPE 3 PRODUCED  
IN VERO CELLS,  
FILAMENTOUS  
HAEMAGGLUTININ,  
DIPHThERIA  
TOXOID, TETANUS  
TOXOID,  
HAEMOPHILUS  
TYPE B  
CONJUGATE  
VACCINE  
(TETANUS TOXOID  
CONJUGATE),  
PERTUSSIS  
TOXOID,  
PERTUSSIS  
FILAMENTOUS  
HAEMAGGLUTININ,  
POLIOVIRUS TYPE  
1 (INACTIVATED),  
POLIOVIRUS TYPE  
2 (INACTIVATED),  
POLIOVIRUS TYPE  
3 (INACTIVATED),  
DIPHThERIA  
TOXOID, TETANUS  
TOXOID,  
HAEMOPHILUS  
TYPE B  
CONJUGATE  
VACCINE  
(TETANUS TOXOID  
CONJUGATE),  
PERTUSSIS  
TOXOID,  
PERTUSSIS  
FILAMENTOUS  
HAEMAGGLUTININ,  
POLIOVIRUS TYPE  
1 (INACTIVATED),  
POLIOVIRUS TYPE  
2 (INACTIVATED),  
POLIOVIRUS TYPE  
3 (INACTIVATED),  
ALGELDRATE,  
DIPHThERIA  
TOXOID, TETANUS  
TOXOID,  
HAEMOPHILUS  
TYPE B  
CONJUGATE  
VACCINE  
(TETANUS TOXOID  
CONJUGATE),  
PERTUSSIS  
TOXOID,  
PERTUSSIS  
FILAMENTOUS  
HAEMAGGLUTININ,  
POLIOVIRUS TYPE  
1 (INACTIVATED),  
POLIOVIRUS TYPE  
2 (INACTIVATED),  
POLIOVIRUS TYPE  
3 (INACTIVATED),  
ALUMINIUM  
HYDROXIDE,  
DIPHThERIA  
TOXOID, TETANUS  
TOXOID,  
HAEMOPHILUS  
TYPE B  
CONJUGATE  
VACCINE  
(TETANUS TOXOID  
CONJUGATE),  
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,  
ALUMINIUM  
HYDROXIDE,  
FILAMENTOUS  
HAEMAGGLUTININ,  
DIPHThERIA  
TOXOID, TETANUS  
TOXOID,  
HAEMOPHILUS

												TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), 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, ALUMINIUM HYDROXIDE, DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, 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 HYDROXIDE, FILAMENTOUS HAEMAGGLUTININ, DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, POLIOVIRUS TYPE 1 (INACTIVATED), POLIOVIRUS TYPE 2 (INACTIVATED), POLIOVIRUS TYPE 3 (INACTIVATED), ALUMINIUM HYDROXIDE, FILAMENTOUS HAEMAGGLUTININ, DIPHThERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, POLIOVIRUS TYPE 1 (INACTIVATED), POLIOVIRUS TYPE 2 (INACTIVATED), POLIOVIRUS TYPE 3 (INACTIVATED)] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10011249007	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Influenza (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-	13/01/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Fatigue (n/a -	COMIRNATY	Not reported	<a href="#">ICSR</a>	



10011249921			Healthcare Professional	Economic Area	available	Month				Recovering/Resolving - ), Injection site pain (1d - Recovering/Resolving - ), Nausea (1d - Recovering/Resolving - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011258057	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Diffuse alopecia (2mo - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>
EU-EC-10011258474	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dysgeusia (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ), Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011228283	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Exposure via breast milk (1d - Recovered/Resolved - ), Infant irritability (1d - Recovered/Resolved - ), Somnolence (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011230433	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (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	<a href="#">ICSR</a>
EU-EC-10011240981	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Unknown - ), Limb discomfort (0d - Unknown - ), Lymphadenopathy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011244232	12/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011213853	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Influenza like illness (3d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011215487	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (1d - Recovered/Resolved - Disabling), Fatigue (1d - Recovered/Resolved - Disabling), Maternal exposure during breast feeding (1d - Recovered/Resolved - Disabling), Nausea (1d - Recovered/Resolved - Disabling), Vomiting (1d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>





EU-EC-10011202132	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important Condition), Infantile vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011202265	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[MEASLES VIRUS EDMONSTON-ENDERS STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, MUMPS VIRUS RIT 4385 STRAIN (LIVE, ATTENUATED) DERIVED FROM FROM THE JERYL LYNN PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS, MEASLES VIRUS EDMONSTON-ENDERS STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS, MUMPS VIRUS RIT 4385 STRAIN, DERIVED FROM JERYL LYNN STRAIN (LIVE, ATTENUATED), MEASLES VIRUS EDMONSTON-SCHWARZ STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, MUMPS VIRUS RIT 4385 STRAIN (LIVE, ATTENUATED) DERIVED FROM FROM THE JERYL LYNN PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS, MEASLES VIRUS EDMONSTON-SCHWARZ STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN	<a href="#">ICSR</a>

HUMAN DIPLOID (MRC-5) CELLS, MUMPS VIRUS RIT 4385 STRAIN, DERIVED FROM JERYL LYNN STRAIN (LIVE, ATTENUATED), MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), MUMPS VIRUS (LIVE, ATTENUATED), RUBELLA VIRUS (LIVE, ATTENUATED), MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), MUMPS VIRUS RIT 4385 STRAIN (LIVE, ATTENUATED) DERIVED FROM FROM THE JERYL LYNN PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS, MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS, MUMPS VIRUS RIT 4385 STRAIN, DERIVED FROM JERYL LYNN STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN WI-38 HUMAN DIPLOID LUNG FIBROBLASTS, MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), MUMPS VIRUS RIT 4385 STRAIN, DERIVED FROM JERYL LYNN STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED), MEASLES VIRUS EDMONSTON-ENDERS STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, MUMPS VIRUS RIT 4385 STRAIN (LIVE, ATTENUATED) DERIVED FROM FROM THE JERYL LYNN PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED), MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), MUMPS VIRUS RIT 4385 STRAIN (LIVE,

												ATTENUATED) DERIVED FROM FROM THE JERYL LYNN PRODUCED IN CHICK EMBRYO CELLS, RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED), MEASLES VIRUS SCHWARZ STRAIN (LIVE, ATTENUATED), MUMPS VIRUS RIT 4385 STRAIN, DERIVED FROM JERYL LYNN STRAIN (LIVE, ATTENUATED)] (C - n/a - n/a - [1d - n/a - n/a]),  [VARICELLA VIRUS OKA/MERCK STRAIN (LIVE, ATTENUATED), VARICELLA VIRUS OKA/MERCK STRAIN, (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS] (C - n/a - n/a - [1d - n/a - n/a])		
EU-EC-10011200041	09/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011191829	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Crying (n/a - Not Recovered/Not Resolved - Disabling),  Diarrhoea neonatal (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Restlessness (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011193264	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Faeces discoloured (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary - More in ICSR])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10011181271	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),  Asthenia (n/a - Not Recovered/Not Resolved - ),  Chest pain (n/a - Not Recovered/Not Resolved - ),  Ear pain (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[CAPTOPRIL] (C - Hypertension - n/a - [n/a - n/a - Oral]),  [EXTRACT (1:11) OF GENTIAN ROOT CUT, VERBENA HERB CUT, COMMON SORREL HERB CUT, ELDER FLOWER RUBBED, PRIMULA FLOWER WITH CALYX CUT; (1:3:3:3:3), EXTRACTION SOLVENT: ETHANOL, 59% (V/V), GENTIAN ROOT, GENTIAN	<a href="#">ICSR</a>	

												ROOT, VERBENA HERB, COMMON SORREL HERB, PRIMULA FLOWER WITH CALYX, SAMBUCUS NIGRA FLOWER, RUMEX, GENTIANA LUTEA, SAMBUCUS NIGRA L., VERBENA, PRIMULA VERIS FLOWER, SAMBUCCI FLOS, GENTIAN ROOT, PRIMULA FLOWERS, GARDEN SORREL HERB, VERBENA OFFICINALIS, SAMBUCCI FLOS, GENTIAN ROOT, VERBENA HERB, COMMON SORREL HERB, PRIMULA FLOWER WITH CALYX] (C - Sinusitis - n/a - [n/a - n/a - Oral])		
EU-EC-10011181938	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Diarrhoea (n/a - Recovered/Resolved - ), Pyrexia (36h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011185062	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011164089	05/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Screaming (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011164534	05/01/2022	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 - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011164570	05/01/2022	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 - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011170831	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), 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	<a href="#">ICSR</a>	
EU-EC-10011173809	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abdominal pain (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Frequent bowel movements (n/a - Recovered/Resolved - ), Restlessness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10011158927	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - ), Haematochezia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-	03/01/2022	Spontaneous	Non	European	Not	0-1	Neonate	Female	Yes	Haemolytic anaemia	COMIRNATY	Not reported	<a href="#">ICSR</a>	

10011147467			Healthcare Professional	Economic Area	available	Month	(Preterm and Term newborns)			(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Premature baby (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental])		
EU-EC-10011148013	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Pyrexia (n/a - Recovered/Resolved - ), Seizure (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>

    Rows 501 - 557 (end)

[Return](#) - [Refresh](#) - [Print](#) - [Export](#)