Line Listing Report Time run: 30/11/2022 03:49:59

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	Child	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011433076	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011433743	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Body temperature increased (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Injection site pain (0d - Recovered/Resolved -)			
EU-EC- 10011434034	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011434057	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011434535	30/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011434543	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Body temperature increased (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011435546	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Night sweats (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011435985	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011436366	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthritis (n/a - Not Recovered/Not Resolved -), Arthritis reactive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011425698	29/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Circumoral oedema (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a2mL - n/a])	Not reported	ICSR
										Periorbital swelling (1d - Recovered/Resolved -),			
										Urticaria (1d - Recovered/Resolved -)			
EU-EC- 10011425840	29/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hyperpyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011425906	29/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -),		Not reported	ICSR
	2015: 17									Myalgia (2d - Recovered/Resolved -)			
EU-EC- 10011425986		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a1mL - Intramuscular])		ICSR
EU-EC- 10011426046	29/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pulse absent (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Respiratory arrest (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (0d - Recovered/Resolved -			

J.11.2022 (J3.33								un Lii	ie Listing Report	1	ı	
										Caused/Prolonged Hospitalisation)			
EU-EC- 10011427220	29/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										- Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rhinovirus infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011427436	29/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not			
EU-EC- 10011427952	29/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Irregular sleep wake rhythm disorder (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Product administered to patient of inappropriate age (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Supraventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011429963	29/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011410311		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10011410312	28/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSR
										Recovering/Resolving		[LYOPHILIZED BACTERIAL LYSATES, LYOPHILIZED BACTERIAL LYSATES OF: HAEMOPHILUS INFLUENZAE STREPTOCOCCUS (DIPLOCOCCUS) PNEUMONIAE AND 0ZAENAE STAPHYLOCOCCUS AUREUS STAPHYLOCOCCUS PYOGENES AND VIRIDANS MORAXELLA (BRANHAMELLA / NEISSERIA) CATARRHALIS] (C - n/a - n/a - [n/a - n/a	
EU-EC-	28/01/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Erythema (n/a -	COMIRNATY [TOZINAMERAN]	[SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]) Not reported	ICSR
10011410321			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Night sweats (n/a - Recovered/Resolved -	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		
), Rash macular (n/a - Recovered/Resolved -),			
										Vertigo (n/a - Recovered/Resolved -)			
EU-EC- 10011410491	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (16d - Recovered/Resolved -), Rash (16d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011410638	28/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved -) Pruritus (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional		3.3.000	.3373	2,50,100), Urticaria (n/a - Recovered/Resolved -	Unknown - [n/a2mL - Intramuscular])		
EU-EC-	28/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Hypoaesthesia (21d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

0.11.2022 (03.53							R	un Lir	ie Listing Report			
10011410896			Healthcare Professional		available	Years				Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Paraesthesia (21d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10011413703	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Constipation (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Decreased appetite (n/a - Recovered/Resolved -),			
										Fatigue (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -)			
EU-EC- 10011414286	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a2mL - Intramuscular])	Not reported	<u>ICSR</u>
										Myalgia (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011414300	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Disturbance in attention (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Subcutaneous])	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved -),			
										Lethargy (n/a - Recovered/Resolved -)			
EU-EC- 10011414303	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a2mL - Intramuscular])	Not reported	<u>ICSR</u>
										Arthralgia (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
EU-EC-	20/01/2022	Spontaneous	Non	European	Not	3-11	Child	Ma l e	No	Vomiting (n/a - Recovering/Resolving -) Pain in extremity (3d	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011414481	26/01/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Crilla	Мане	No	- Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	<u>ICSK</u>
EU-EC- 10011415824	28/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Female	No) Fatigue (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area), Injection site pain (2d - Recovered/Resolved	- n/a - n/a])		
EU-EC- 10011415897	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	-) Fatigue (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011417357	28/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Abdominal pain (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d2mL -	Not reported	ICSR
										Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011417651	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Muscular weakness (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Pain in extremity (n/a - Recovering/Resolving			
EU-EC- 10011419735	28/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a - Unknown -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	ICSR
			riolessional	Area						Nausea (n/a - Unknown -)	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a2mL - n/a])		
EU-EC- 10011419923	28/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	<u>ICSR</u>
			Professional	Area						Resolved -)	CONCENTRATE FOR		

0.11.2022 (03.53							K	un Lir	ie Listing Report			
											DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011421881	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cold sweat (10min - Recovered/Resolved -), Pallor (10min - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (10min - Recovered/Resolved -			
EU-EC- 10011422069	28/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10011422135	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Injection site pain (1d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10011422378	28/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a2mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC- 10011422379	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (6h - Recovered/Resolved -), Vomiting (6h - Recovered/Resolved -	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
EU-EC- 10011422489	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Mouth swelling (n/a - Unknown -)	applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 10ug -	Not reported	ICSR
EU-EC- 10011423019	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (0d - Recovering/Resolving	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011423027	28/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011423042	28/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011423084	28/01/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Child	Male	No	Chills (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -),			
										Influenza (0d - Recovered/Resolved -),			
										Injection site pain (3d - Recovered/Resolved -),			
										Limb discomfort (0d - Recovered/Resolved -),			
										Lymphadenopathy (2d - Recovered/Resolved -),			
										Malaise (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011423086	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved -			
EU-EC- 10011423088		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011423095	28/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	Yes	COVID-19 (1d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-	28/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Oedema peripheral	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011424684			Professional	Economic Area	available	Years				(2d - Recovered/Resolved -),	(S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])		
										Rash (n/a - Recovering/Resolving			
EU-EC- 10011425284	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Ma l e	No	Chest pain (16d - Not Recovered/Not Resolved -), Dyspnoea exertional	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										(16d - Not Recovered/Not Resolved -)			
EU-EC- 10011398607	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (5d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
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10011398713		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	- Recovered/Resolved -)	- n/a - n/a])		ICSF
EU-EC- 10011398752	27/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (2d - Recovering/Resolving -), Limb discomfort (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										- Recovering/Resolving			
										Nausea (2d - Recovering/Resolving -)			
EU-EC- 10011398897	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Fatigue (10min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])	Not reported	ICSF
										Palpitations (10min - Recovered/Resolved -)			
EU-EC- 10011399018			Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Oral herpes (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		ICSR
EU-EC- 10011399028	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
										Lymph node pain (n/a - Recovered/Resolved -), Lymphadenopathy			
										(n/a - Recovered/Resolved -			
EU-EC- 10011399071	27/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSF
										Decreased appetite (n/a - Not Recovered/Not Resolved -),			
										Dizziness (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved -),			
										Paraesthesia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vertigo (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011399198			Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		ICSF
EU-EC- 10011399201	27/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (1d - Recovered/Resolved -	(S - COVID-19 immunisation - n/a - [n/a2mL -	[CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
				Area			1			1)	Inframusculari)	[I ANSOPRAZOI F1 (C = n/a .	
				Area							Intramuscular])	[LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a -	
				Area							Intramuscular])	n/a - [n/a - n/a - n/a]),	

Professional Area Resolved -), Not applicable - [n/a - 1{DF} n/a])	J.11.2022 C									un Lii	ne Listing Report			
1901-1909 Professional Common Secretary Common														
2011/10/2015 2011/2015 2		27/01/2022	Spontaneous		Economic				Female	No	(1d -	(S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSR
27611/2002 27611/2002 250		27/01/2022	Spontaneous		Economic				Female	No	(1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSR
EUC-C 17/10/202 Sportbrown Machboard European Modern		27/01/2022	Spontaneous		Economic				Female	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
March Marc											Recovered/Not Resolved -)	2,		
Professional Pro		27/01/2022	Spontaneous		Economic				Male	No	Recovered/Not	(S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
Part		27/01/2022	Spontaneous		Economic				Male	No	Recovered/Not Resolved -), Vaccination site reaction (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
SU-SC 27(01/2022 Spontamenus levelstrans Roughous Library (174) and the second process of the second process o		27/01/2022	Spontaneous		Economic				Male	No	Hyperaemia (n/a - Recovering/Resolving	(S - COVID-19 immunisation -	Not reported	ICSR
EU-FC. 2701/2022 Sportaneous Medicare Roberts Professional Roberts Prof											Injection site pustule (n/a - Recovering/Resolving	Intramuscular])		
EU-EC- 10011401330 2/01/2022 Spontaneous Non- Nethorare European Not Professional Recovering Resolving - 1 EU-EC- 10011401331 2/01/2022 Spontaneous Non- Nethorare European Not Recovering Resolving - 1 EU-EC- 10011401331 2/01/2022 Spontaneous Non- Nethorare European Not Recovering Resolving - 1 EU-EC- 10011401331 2/01/2022 Spontaneous Non- Nethorare European Not Recovering Resolving - 1 EU-EC- 10011401331 2/01/2022 Spontaneous Non- Nethorare European Not Recovering Resolving - 1 Not Recovered Not Resolved - 1 Not Resolved - 1 Not Recovered Not Resolved - 1 Not Recovered Not Reco											Oedema peripheral (n/a - Recovering/Resolving			
EU-EC- 10011399305 27/01/2022 Spontaneous Healthcare Economic Professional Profess											Pain in extremity (n/a - Recovering/Resolving			
EU-EC- 10011399636 27/01/2022 Spontaneous Healthcare European Area Professional Profes											Vaccination site injury (n/a - Recovering/Resolving			
Professional Professional Conomic Area Professional Conomic Area Professional											Vaccination site vesicles (n/a -			
EU-EC- 10011401530 27/01/2022 Spontaneous Non Healthcare Professional Area Not Recovered/Not Recovered/N		27/01/2022	Spontaneous		Economic				Male	No	Recovering/Resolving -),	(S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSR
EU-EC- 10011401531 27/01/2022 Spontaneous Non Healthcare Professional Area Not Recovered/Not Resolved - J, Not R											(n/a - Recovering/Resolving			
EU-EC- 10011401531 Z//01/2022 Spontaneous Professional Realthcare Recovered/Not Resolved -) Not Resolv											(n/a - Recovering/Resolving			
Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Vaccination site vesicles (n/a - Not Recovered/Not Rec											Recovering/Resolving			
EU-EC- 10011401530 EU-EC- 10011401531 EU-FC- 10011401530 EU-FC- 10011401530 EU-FC- 10011401530 EU-FC- 10011401530 EU-FC- 10011401530 EU-FC- 10011401530 EU-FC- 10011401531 EU-FC-											Recovering/Resolving -),			
EU-EC- 10011401530											Recovering/Resolving -),			
Healthcare Professional Healthcare Profe											vesicles (n/a -			
EU-EC- 10011401531 Spontaneous Professional		27/01/2022	Spontaneous	Healthcare	Economic				Male	No	Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
Healthcare Professional Area Healthcare Professional Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -) Myalgia (n/a - Not Recovered/Not Resolved -)	FILEC	27/01/2022	Chantanasus	Non	Funancan	Not	2.11	Not	Mele	No	Recovered/Not Resolved -)	COMIDNATY [TOTINAMEDAN]	COMIDNATY [TOZINAMEDAN]	ICCD
Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Recovered/Not Resolved -)		27/01/2022	apontaneous	Healthcare	Economic				ı™dle	INO	Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	(C - n/a - n/a - [n/a - n/a -	ICSR
Resolved -)											Recovered/Not Resolved -), Myalgia (n/a - Not			
		27/01/2022	Spontaneous		European	Not	3-11	Child	Female	No	Resolved -) Abdominal pain upper	COMIRNATY CONCENTRATE	Not reported	ICSR
10011401682 Healthcare Economic Area Professional Area Healthcare Professional Area Professional Area Professional Area Professional Area Professional P	10011401682					available	Years				Recovered/Resolved -	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]		

0.11.2022 (33.33							11	un Lii	ne Listing Report			
										-), Diarrhoea (3d - Recovered/Resolved -	Not applicable - [n/a - 10ug - n/a])		
), Dizziness (3d - Recovering/Resolving -),			
										Headache (3d - Recovering/Resolving			
EU-EC- 10011403971	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Gait disturbance (3d - Recovered/Resolved - Disabling), Pain in extremity (3d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [0d2M[iU] - Intramuscular])	Not reported	ICSR
										- Recovered/Resolved - Disabling)			
EU-EC- 10011404312	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - 1{DF} - Intramuscular])	Not reported	ICSR
										Diplopia (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Muscle twitching (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vertigo (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011404389			Healthcare Professional		Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011404475	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -)			
EU-EC- 10011405538	27/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Exposure to SARS- CoV-2 (n/a - Unknown -),			
EU-EC-	27/01/2022	Spontaneous	Non	Non	Not	3-11	Not	Female	No	Nasal congestion (n/a - Unknown -) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011405901	27/01/2022	Sportaneous	Healthcare Professional	European	available	Years	Specified	remale	NO	Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	Not reported	ICSK
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE		
										Dysmenorrhoea (n/a - Unknown -), Heavy menstrual			
										bleeding (n/a - Not Recovered/Not Resolved -),	(H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014,		
										Menstruation irregular (n/a - Unknown -),	X-263B), B/BRISBANE/60/2008-LIKE STRAIN		
										Nodule (n/a - Recovered/Resolved -),	(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015,		
										Pain in extremity (n/a - Recovered/Resolved -),	IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a])		
										Peripheral swelling (n/a - Recovered/Resolved -),	,		
										Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011406011	27/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	Yes	Condition) Deafness unilateral (1wk - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [0d2mL -	Not reported	ICSR
EU-EC- 10011406771	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Disabling) Hemihypoaesthesia (n/a - Unknown - Other Medically Important Condition),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR

U.11.2022 (un Lir	ne Listing Report			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Injected limb mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011406925	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	Yes	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011406951	27/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011409403	27/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lacrimation increased (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - (n/a - n/a - Intramuscular])	Not reported	ICSR
										Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important			
EU-EC- 10011409441	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Condition) Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011409513	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011409955	27/01/2022	Spontaneous	Non Hea l thcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Cholestasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Hepatitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011411560	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESLORATADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]),	ICSR
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	
EU-EC- 10011411711		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011411745	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Henoch-Schonlein purpura (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011411778	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Diarrhoea (n/a - Recovering/Resolving -)			
EU-EC- 10011411977	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011411992	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arrhythmia (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Epilepsy - Unknown - [n/a -	ICSR
										Chest pain (1d - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition),			
						1			1	Tachycardia (1d -			

.11.2022 C 	.0.00									Recovered/Resolved	[
										Other Medically Important Condition)			
EU-EC- 10011412038	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	IC
EU-EC- 10011412584	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Elderly	Male	No	Peripheral coldness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10011412588	27/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Arrhythmia (2d - Recovered/Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Influenza (5d - Recovered/Resolved -),			
										Tachycardia (4d - Recovered/Resolved -)			
0011412663		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (36d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		IC
.0011412670		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	,	IC
U-EC- 0011386475	26/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Infusion site reaction (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	IC
										Injection site erythema (n/a - Recovering/Resolving -),			
										Injection site haematoma (n/a - Recovering/Resolving -),			
										Injection site pruritus (n/a - Recovering/Resolving -)			
U-EC- 0011387266	26/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	<u>I</u> 0
										Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a -			
:U-EC- .0011387332	26/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Eye pruritus (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	10
				Area), Eyelid oedema (0d - Recovered/Resolved -	n/a - [n/a - n/a - Intramuscular])		
										Larynx irritation (0d - Recovered/Resolved -)			
EU-EC- 10011388327	26/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Generalised tonic- donic seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, PHENYLPROPANOLAMINE HYDROCHLORIDE] (C - Cough, Nasopharyngitis - n/a - [4d - n/a - n/a])	
U-EC- 0011388637	26/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	10
										Dysphonia (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Oropharyngeal pain (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
71.50	26/64 :					2.1.				Rhinitis (n/a - Recovering/Resolving -)	COMPANIE CE		
EU-EC- 10011388999	26/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	IC

									Visual impairment			
									(n/a - Recovered/Resolved -			
									Other Medically Important Condition), Vomiting (n/a -			
									Recovered/Resolved - Other Medically Important Condition)			
		Healthcare Professional	Economic Area	available	Years				- Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
26/01/2022	Spontaneous			available	Years	Specified	remaie	INO	Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Recovered/Resolved -	(G - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	not reported	<u>ICS</u>
									Wrong product administered (n/a - Recovered/Resolved -)			
26/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
		Healthcare Professional	Area	Not available	3-11 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
26/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(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	3
26/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
26/01/2022	Spontaneous			Not available	3-11 Years	Child	Male	No	Rash maculo-papular (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICS
26/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
26/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
26/01/2022	Spontaneous	Non Hea l thcare	European Economic	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved		Not reported	ICS
26/01/2022	Spontaneous	Healthcare		Not available	3-11 Years	Child	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
26/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (0d - Recovering/Resolving -), Pyrexia (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
20 20 20 20 20 20 20 20 20 20 20 20 20 2	6/01/2022 6/01/2022 6/01/2022 6/01/2022 6/01/2022 6/01/2022	6/01/2022 Spontaneous	Professional Professional Professional Professional Professional Professional Professional	Healthcare Professional Area European Professional Area	Healthcare European Not available	Healthcare Professional Area 6/01/2022 Spontaneous Non Healthcare Professional Area	Heathcare Professional Profess	Healthcare Professional Realthcare Realthcare Professional Realthcare Professional Realthcare Professional Recommic Re	Healthcare Professional Area Not Specified Female No	Sportaneous Non	Montange Montange	March

7.11.2022			I		1	I	1	1		Recovering/Resolving	1	1	
EU-EC-	26/01/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	-) Henoch-Schonlein	 COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011395365	20,02,202	Sportaniosas	Healthcare Professional	Economic	available	Years	O.M.			purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - 1{DF} - n/a])		100
EU-EC- 10011395525	26/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10011395603	26/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Important Condition) Hand-foot-and-mouth disease (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011395627	26/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSI
EU-EC- 10011395630	26/01/2022	Spontaneous	Healthcare	Area European Economic	Not available	3-11 Years	Child	Male	No	Epistaxis (n/a - Recovering/Resolving	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSI
EU-EC- 10011395632	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (0d - Recovered/Resolved -),	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Headache (1d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved -),			
										Injection site swelling (1d - Recovered/Resolved -)			
EU-EC- 10011395636	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011395640	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICS
FIL FO	25 (01 (2022	Constant	Lisa Misa a sa	F	Note	2.44	Child	Mala	Nie	Syncope (0d - Recovering/Resolving - Other Medically Important Condition)	COMPNAT/ (TOTALAMED AND		Icci
EU-EC- 10011395983	26/01/2022	Spontaneous	Professional		Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	NOL reported	ICSF
										-), Vaccination site pruritus (n/a - Recovering/Resolving -), Vaccination site swelling (n/a - Recovering/Resolving			
EU-EC- 10011396008	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Abdominal pain upper (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSI
										-), Decreased appetite (n/a - Recovering/Resolving -),	- n/a])		
										Headache (n/a - Recovering/Resolving -)			
EU-EC- 10011396158	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011396165	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	- Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
EU-EC- 10011396175	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No		n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
										Presyncope (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011396179	26/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Child	Female	No	Vaccination site erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF

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				Area						Unknown -), Vaccination site pain	Not applicable - [1d - 1{DF} - n/a])		
				_				ļ		(n/a - Unknown -)			ļ.,
EU-EC- 10011396180	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011396183	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
										Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
	25/04/2022			-		2.44				Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			100
10011396189		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	·	ICS
EU-EC- 10011396191	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011396193	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
										Headache (2d - Recovered/Resolved -),			
										Vaccination site pain (2d - Recovered/Resolved -)			
10011396197		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (16d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])		ICS
EU-EC- 10011396202	26/01/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011396261	26/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
511 50	25/04/2022							ļ		Recovered/Resolved - Other Medically Important Condition)			1.00
EU-EC- 10011396280	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Atopy (n/a - Recovering/Resolving -), Dermatitis atopic (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										- Recovering/Resolving			
EU-EC- 10011396282	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[MICONAZOLE, MICONAZOLE NITRATE, MICONAZOLE NITRATE, HYDROCORTISONE] (C - n/a - n/a - [14d - n/a - Cutaneous])	ICS
EU-EC- 10011396290	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthritis reactive (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]),	Not reported	ICS
										Joint effusion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Joint effusion (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Unknown - Caused/Prolonged			
EU-EC- 10011396322	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hospitalisation) Petechiae (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICS
EU-EC- 10011396902	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Myalgia (4d - Recovered/Resolved -),	- Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS

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EU-EC-	26/01/2022	Spontaneous		European	Not	3-11	Elderly	Female	No	- Recovered/Resolved -) Asthenia (25d - Not		Not reported	ICS
10011397030			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -), Erythema (25d - Not Recovered/Not	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Resolved -), Headache (25d - Not Recovered/Not			
										Resolved -), Influenza (25d - Not Recovered/Not			
										Resolved -), Palpitations (25d - Not Recovered/Not			
EU-EC- 10011397059	26/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Adult	Female	No	Resolved -) Dizziness (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
10011397039			Professional		available	lears), Injection site pain (3d - Recovered/Resolved	- n/a - Intramuscular])		
EU-EC- 10011397101	26/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Dizziness (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
			Professional	Area						Injection site pain	- n/a - n/a])		
										Recovering/Resolving -),			
										Myalgia (n/a - Recovering/Resolving -),			
				_				<u> </u>		Pyrexia (0d - Recovering/Resolving -)			
EU-EC- 10011397159	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (3d - Recovering/Resolving -),			
										Injection site pain (2d - Recovered/Resolved -)			
EU-EC- 10011397160	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011397175	26/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site erythema (n/a - Unknown -),			
										Injection site pain (n/a - Unknown -),			
										Injection site swelling (n/a - Unknown -)			
EU-EC- 10011397183	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (0d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (0d - Not Recovered/Not Resolved -),			
										Pyrexia (0d - Unknown -)			
EU-EC- 10011397194	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Nausea (13d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011397213		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011397234	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011397273	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011397308	26/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	Rash (21d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011397438	26/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Influenza (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (0d - Recovered/Resolved -)			
EU-EC- 10011397509		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Rash (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011397548	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (9d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (3d - Not			

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										Recovered/Not Resolved -),			
										Lymphadenopathy (2d - Not Recovered/Not			
EU-EC-	26/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Resolved -) Nausea (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011397555	,,		Healthcare Professional	Economic	available	Years				Recovering/Resolving -),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Vomiting (1d - Recovering/Resolving -)			
EU-EC- 10011397624	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	- Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC-	26/01/2022	Spontaneous		European	Not	3-11	Child	Female	No	Fatigue (0d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011397631			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -), Fatigue (0d -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Unknown -), Headache (0d - Recovering/Resolving -),			
										Injection site pain (1d			
										- Recovering/Resolving			
EU-EC-	26/01/2022	Spontaneous		European	Not	3-11	Child	Female	No	-) Influenza (2d - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011397640			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -), Myalqia (2d - Not	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Not Resolved -)			
EU-EC- 10011397654	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (3d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (3d - Not Recovered/Not Resolved -),			
										Vomiting (2d - Recovered/Resolved -			
EU-EC- 10011397696	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (0d - Recovered/Resolved -),			
										Injection site pain (2d - Unknown -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011372850	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperpyrexia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Nightmare (n/a - Recovering/Resolving -),			
										Somnambulism (n/a - Recovering/Resolving -)			
EU-EC- 10011372876	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Confusional state (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved -),	intrantoscular j)		
										Hot flush (n/a - Recovered/Resolved -),			
										Peripheral coldness (n/a - Recovered/Resolved -			
), Pyrexia (n/a -			
										Recovered/Resolved -), Vomiting (n/a -			
_										Recovered/Resolved -)			
EU-EC- 10011372909	25/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Syncope (0d - Recovered/Resolved - Other Medically			
EU-EC-	25/01/2022	Spontaneous		European	Not	3-11	Not	Female	No	Important Condition) Chest discomfort (n/a		Not reported	ICSR
10011373037			Healthcare Professional	Economic Area	available	Years	Specified			- Recovering/Resolving -),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										"			

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										Chest pain (n/a - Recovering/Resolving -), Heavy menstrual			
										bleeding (n/a - Recovering/Resolving -), Pain (n/a -			
EU-EC-	25/01/2022	Spontaneous		European	Not	3-11	Not	Male	No	Recovering/Resolving -) Injection site	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011373121		·	Professional	Economic Area	available	Years	Specified			erythema (n/a - Recovering/Resolving -), Injection site	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										haematoma (n/a - Recovering/Resolving -),			
										Injection site necrosis (n/a - Recovering/Resolving -),			
										Injection site oedema (n/a - Recovering/Resolving -),			
										Injection site pain (n/a - Recovering/Resolving -),			
										Vaccination site reaction (n/a - Recovering/Resolving -)			
EU-EC- 10011373146		Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10011373451		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving -)	(S - n/a - n/a - [n/a - 10ug - Intramuscular])	·	ICSR
EU-EC- 10011373752	25/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved -), Fatigue (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Headache (3d - Recovered/Resolved -			
EU-EC- 10011373753	25/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10uq - Intramuscular])	[INSULIN, INSULIN HUMAN] (C - Type 1 diabetes mellitus - n/a - [n/a - 36[iU] - Subcutaneous])	ICSR
EU-EC- 10011373754	25/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved -), Headache (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[INSULIN, INSULIN HUMAN]	ICSR
										Recovered/Resolved -), Injection site pain (3d			
EU-EC-	25/01/2022	Spontaneous		European	Not	3-11	Not	Female	No		COMIRNATY [TOZINAMERAN]	[AZITHROMYCIN] (C - n/a -	ICSR
10011373755			Professional	Area	available	Years	Specified			- Recovered/Resolved -), Pyrexia (7d - Recovered/Resolved -	(S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	n/a - [n/a - n/a - n/a]), [DORNASE ALFA] (C - Cystic fibrosis - n/a - [n/a - 2.5mg - Respiratory (inhalation)]),	
), Somnolence (7d - Recovered/Resolved -		[PANCREALIPASE] (C - Cystic fibrosis - n/a - [n/a - 12{DF} - Oral])	
EU-EC- 10011373756	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[DORNASE ALFA] (C - Cystic fibrosis - n/a - [n/a - 2.5mg - Respiratory (inhalation)]),	ICSR
										Fatigue (5d - Recovered/Resolved -),		[PANCREALIPASE] (C - Cystic fibrosis - n/a - [n/a - 12{DF} - n/a])	
										Irritability (5d - Recovered/Resolved -),			
										Somnolence (5d - Recovered/Resolved -)			
EU-EC- 10011373757	25/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	- Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[FOLIC ACID, ANHYDROUS] (C - n/a - n/a - [n/a - 5mg - Oral]), [METHOTREXATE] (C -	ICSR
EU-EC-	25/01/2022	Sportaneous	Haalthaara	European	Not	3-11	Not	Female	No	Nasopharyngitis (5d - Recovered/Resolved -) Headache (4d -	COMIDNATY ITOTINAMED AND	Rheumatoid arthritis - n/a - [n/a - n/a - n/a])	ICCD
10011373758	23/01/2022	Spontaneous	Professional		available	Years	Specified	remale	INO	Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[FOLIC ACID, ANHYDROUS] (C - n/a - n/a - [n/a - 5mg - Oral]),	ICSK
										Injection site pain (4d - Recovered/Resolved -),		[METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a])	

0.11.2022 (un Lir	ie Listing Report			
										Lymphadenopathy (4d - Recovered/Resolved -			
), Myalgia (4d - Recovered/Resolved -			
										Pyrexia (4d - Recovered/Resolved -			
EU-EC- 10011373769	25/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Area						Injection site pain (2d - Recovered/Resolved	Dose not changed - [n/a - 10ug - Intramuscular])		
EU-EC- 10011373770	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nasopharyngitis (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[CARBAMAZEPINE] (C - Epilepsy - n/a - [n/a - 18mL - Oral])	ICSR
										Rhinorrhoea (6d - Recovered/Resolved -)	Todg Indumuscular J		
EU-EC- 10011375634	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Asthenia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011375940	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (1h - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	Not reported	<u>ICSR</u>
										Rash (1h - Recovered/Resolved -	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011377158		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011377220	25/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011377374	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a2mL - Intramuscular])	Not reported	<u>ICSR</u>
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011378668	25/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Pyrexia (1h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug -	Not reported	ICSR
										Vomiting (10h - Recovered/Resolved -	n/a])		
EU-EC- 10011379366	25/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (12h - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	ICSR
										Loss of personal independence in daily activities (n/a - Recovered/Resolved -	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011379806	25/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
										Hyporesponsive to stimuli (n/a - Recovering/Resolving	- n/a])		
										Panic attack (n/a - Recovering/Resolving			
EU-EC- 10011380932	25/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	-)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011381284	25/01/2022	Spontaneous		Area European Economic	Not available	3-11 Years	Not Specified	Female	No	Epilepsy (0d - Recovering/Resolving	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC-	25/01/2022	Spontaneous	Professional		Not	3-11	Child	Male	No	- Other Medically Important Condition) Hallucination (1d -	Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011382317	, ,		Healthcare Professional	Economic	available	Years				Recovered/Resolved -),	(S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])		
										Influenza like illness (1d - Recovered/Resolved -			
EU-EC- 10011384779	25/01/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Female	No	Myositis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
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EU-EC- 10011385260	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Unknown -) Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
EU-EC- 10011385289	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Erythema (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Vomiting (2d -	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ANHYDROUS FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID PH. EUR., SODIUM FUSIDATE, SODIUM FUSIDATE PH. EUR.] (C - Skin infection - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC- 10011385304	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Recovered/Resolved -) Vaccination site lymphadenopathy (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011385361	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Resolved -) Swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011385365	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESLORATADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a -	ICSR
EU-EC- 10011385447	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Oral]) Not reported	ICSR
EU-EC- 10011385462	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Feeling jittery (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Muscle spasms (3d - Recovered/Resolved -), Tic (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011385730	25/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011385960	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Important Condition) Urticaria (2d - Recovered/Resolved - Other Medically	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d1mL -	Not reported	ICSR
EU-EC- 10011361409	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Important Condition) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011363243	24/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011363749	24/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011363838	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (4d - Recovered/Resolved -	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011363841	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011363874		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	- Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011364863	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR

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										Important Condition), Arthritis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										C-reactive protein increased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Joint effusion (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Petechiae (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	24/01/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011365329	24/01/2022	Spontaneous	Healthcare	Economic	available	Years	Specified	remale	INO	- Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
EU-EC- 10011365426	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site erythema (2d - Recovering/Resolving -),			
										Injection site pain (2d			
EU-EC-	24/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	Recovering/Resolving -) Headache (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011365537	2 1,02,2022	Spontanious	Professional		available	Years	J	, , , ,		Recovering/Resolving -), Neck pain (n/a -	(S - n/a - n/a - [1d - n/a - Intramuscular])	not ropered	2551
										Recovering/Resolving -), Petechiae (n/a - Recovering/Resolving			
EU-EC- 10011365620	24/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	Erythema (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
EU-EC- 10011365676	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Gastrooesophageal reflux disease (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10011368548	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION ITOZINAMERANI (S - COVID-	Not reported	ICSR
										Recovered/Not Resolved -)	19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011368979	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-	Not reported	ICSR
										Pyrexia (n/a -	19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011371782	24/01/2022	Spontaneous	Non Hea l thcare	European Economic	Not available	3-11 Years	Child	Ma l e	No	Unknown -) Lymphadenopathy (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional	Area						Recovering/Resolving -)	Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10011371995		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d1mL - Intramuscular])		ICSR
EU-EC- 10011371999		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011372018	24/01/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovering/Resolving -), Vulvitis (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSK
										Recovering/Resolving -)			
EU-EC- 10011372282	24/01/2022	Spontaneous		Non European	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	<u>ICSR</u>

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

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

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										Somnolence (n/a - Recovering/Resolving			
EU-EC- 10011346478	21/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Rash (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011347099	21/01/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICS
										Malaise (n/a - Not Recovered/Not Resolved -),	- n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011348972	21/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anxiety (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	<u>ICSF</u>
										Depression (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011350170	21/01/2022	Spontaneous			Not available	3-11 Years	Child	Female	No	Hallucination, visual (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF
										Headache (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Urinary incontinence (1d - Recovered/Resolved -)			
EU-EC- 10011350421	21/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Product administered to patient of inappropriate age (n/a - Unknown -)			
EU-EC- 10011350892	21/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Flushing (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Lip swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011350927	21/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011352185	21/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Ear pain (2d -			

30.11.2022	33.33							N	ull Lii	ie Listing Report			
										Recovering/Resolving -), Headache (3d - Recovered/Resolved -			
), Limb discomfort (3d - Recovering/Resolving			
										-), Muscle spasms (2d - Recovering/Resolving -),			
										Myalgia (2d - Recovering/Resolving -),			
										Nausea (3d - Recovered/Resolved -),			
										Pyrexia (2d - Recovering/Resolving -)			
EU-EC- 10011352261		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Myopia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])		ICSR
EU-EC- 10011352479	21/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not			
										Recovered/Not Resolved -), Vomiting (n/a - Not			
EU-EC-	21/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Recovered/Not Resolved -) Pyrexia (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011352570			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011352726		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (7d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])		ICSR
EU-EC- 10011352747	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		ICSR
										Chills (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not			
EII EC	21/01/2022	Caratana	Nan	F	Nat	2.11	Child	Mala	N-	Recovered/Not Resolved -)	COMIDNATY STOTINAMED AND	Networked	ICCD
EU-EC- 10011352772		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])		ICSR
EU-EC- 10011353495		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Male	No	Vasculitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	,	ICSR
EU-EC- 10011353499	21/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011353511	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	,		
										Malaise (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011353514	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important			

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										Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia intercostal			
										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011353515		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Female	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	ICSR
EU-EC- 10011353898	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urinary retention (60min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011353984	21/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011353992	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovered/Resolved -), Vomiting (1d -			
EU 50	24 /04 /2022	Constant	Nico		Not	2.11	A 4.45		NI.	Recovered/Resolved -	COMPNADY (TOTINAMED AND	N. b b. J	TOCO
EU-EC- 10011354021	21/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Adult	Female	No	(1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Chills (n/a - Not Recovered/Not Resolved -),			
										Influenza (n/a - Not Recovered/Not Resolved -), Nausea (1d -			
										Recovered/Resolved -), Skin swelling (7d -			
										Recovered/Resolved -), Vaccination site			
										reaction (7d - Recovered/Resolved -), Vomiting (0d -			
EU-EC-	21/01/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Recovered/Resolved -) Rash (6d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011354040 EU-EC-		Spontaneous	Healthcare Professional	Economic Area	available	Years 3-11	Specified Child	Female		Recovered/Resolved -) Hypokinesia (4h -	(S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]	·	ICSR
10011320571	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	available	Years	Crilla	remale	No	Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Drug withdrawn - [n/a2mL - Intramuscular])	Not reported	<u>ICSK</u>
										Vaccination site pain (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011320755	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
										Agitation (n/a - Recovered/Resolved -),			
										Irritability (n/a - Recovered/Resolved -)			
EU-EC- 10011320756	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	<u>ICSR</u>
										Agitation (n/a - Recovered/Resolved -), Irritability (n/a -			
EU-EC-	20/01/2022	Spontaneous		European	Not	3-11	Not	Female	No	Recovered/Resolved -) Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011320919			Professional	Economic Area	available	Years	Specified			(n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011321012	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

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										Headache (2d - Recovered/Resolved -),	Not applicable - [n/a - 1{DF} - Intramuscular])		
										Pyrexia (2d - Recovered/Resolved -),			
										Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10011321142	20/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSF
										Palpitations (n/a - Recovering/Resolving -)	_		
EU-EC- 10011321193	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Catarrh (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSF
										Cough (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a			
										- Not Recovered/Not Resolved -), Pyrexia (n/a - Not			
EU-EC-	20/01/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Male	No	Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011321661		·	Professional	Economic Area	available	Years	Specified			(n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	·	
EU-EC- 10011321681	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[EPLERENONE] (C - Asthma - n/a - [n/a - n/a - n/a]), [MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a -	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),		n/a])	
										Headache (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Vertigo (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011323382	20/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Exposure to SARS- CoV-2 (n/a - Unknown -),			
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011324492	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d Recovering/Resolving			
EU-EC- 10011324614	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Cough (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011325209	20/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (2d - Recovered/Resolved -	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
EU-EC- 10011325278	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011325289	20/01/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -),	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (1d - Recovered/Resolved -)			
EU-EC- 10011325429	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011325439	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011325785		Spontaneous	Healthcare Professional	1	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011325831	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (1d - Recovering/Resolving -),	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (1d -			

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Part														
Section Sect											- ' ' '			
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Prof. Prof			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Recovered/Not	(S - Immunisation - n/a - [n/a	Not reported	ICSR
											Recovered/Not			
March Marc			20/01/2022	Spontaneous	Healthcare	Economic			Male	No	Recovered/Resolved -	MICROGRAMS/DOSE	Not reported	<u>ICSR</u>
Description					Tolessional	Aica					Tremor (5min -	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not		
1945 1945			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
File Part			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
Reduction (5 - Recovered/Resolved 1			20/01/2022	Spontaneous	Healthcare	Economic			Male	No		(S - Immunisation - n/a - [n/a	Not reported	ICSR
ELH-G- 2001/2022 Sportaneous Non- European Net Section Net N											Recovered/Resolved -	, , , ,		
EU-EC- 20/01/2022 Spontameous Non											Injection site pain (2d - Recovered/Resolved			
											Injection site pain (5d			
EU-EC 2001/2022 Spontaneous Non European Not Healthcare Professional Area Area Non Healthcare Professional Area Non Healthcare Non Healthcare Professional Area Non Healthcare Non Healthcare Professional Area			20/01/2022	Spontaneous	Healthcare	Economic		Child	Ma l e	No		(S - Immunisation - n/a - [n/a	Not reported	<u>ICSR</u>
ELEC. 10011326553 20/01/2022 Spontaneous Non European Not Non Not Non Not Non Not Non Not Non Not Non Not			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
Recovered/Not Resolved - 1											(n/a -			
EU-EC- 10011326551 20/01/2022 Spontaneous Non- Not- European Not- Sconomic Not- Sconomic Not- Sconomic Not- Sconomic Not- Sconomic Not- Not			20/01/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Recovered/Not	(S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011326513 20/01/2022 Spontaneous Non Healthcare Professional Pro					riolessional	Area					Headache (1d - Not Recovered/Not	- 11/a - 11/a] <i>)</i>		
EU-EC- 20/01/2022 Spontaneous Non Healthcare European Not Healthcare Professional Area Non Heal			20/01/2022	Spontaneous	Healthcare	Economic		Chi l d	Male	No	Headache (5d - Not Recovered/Not	(S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 20/01/2022 Spontaneous Non Healthcare Economic Professional Area Mot			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Dizziness (28d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011326791 EU-EC- 10011326791 EU-EC- 10011327182 EU-EC- 10011327202 EU-EC- 10011327203 EU-EC-											Recovered/Not			
EU-EC- 10011326791 20/01/2022 Spontaneous Non Healthcare Professional Area Non Healthcare Professional Not Resolved -) EU-EC- 10011327182 EU-EC- 10011327202 20/01/2022 Spontaneous Non Healthcare Professional Healthcare Professional Area Non Healthcare Professional Area Non Healthcare Professional Non Healthcare Professional Area Non H											Nausea (28d - Not Recovered/Not			
EU-EC- 10011327207 20/01/2022 Spontaneous Non Healthcare Professional Area Not Healthcare Professional Area			20/01/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Abdominal pain (n/a -		Not reported	<u>ICSR</u>
EU-EC- 10011327182 Spontaneous Non Healthcare Professional 1011327222 Spontaneous Non Healthcare Professional 1011327222 Spontaneous Non Healthcare Professional 2001/2022 Spontaneous Non European Not 3-11 Child Male No Chills (n/a - Not Resolved -), Pyrexia (n/a - Not Resolved -), Pyrexia (n/a - Not Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2028 Not reported 2001/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY (TOZINAMERAN) Not reported 2001/2028 Not repor					Professional	Area					Recovered/Not	Intramuscular])		
EU-EC- 10011327182 EU-EC- 10011327207 EU-EC- 10011327202 EU-EC- 20/01/2022 Spontaneous Non European Healthcare Professional European Healthcare Professional European Healthcare Professional European Healthcare Professional European Not European Healthcare Professional European Not European Not European Healthcare Professional Area Not reported ICSR Comirnanty [TOZINAMERAN] Not reported ICSR EU-EC- 10011327202 EU-EC- 10011327202 EU-EC- 20/01/2022 Spontaneous Non EU-EC- 20/01/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY [TOZINAMERAN] Not reported ICSR COMIRNATY [TOZINAMERAN] Not reported ICSR ICSR COMIRNATY [TOZINAMERAN] Not reported ICSR ICS											Hyperhidrosis (n/a -			
EU-EC- 10011327182 20/01/2022 Spontaneous Non Healthcare Professional IEuropean Healthcare Professional IEU-EC- 10011327207 EU-EC- 10011327207 20/01/2022 Spontaneous Non Healthcare Professional IEuropean Healthcare Professional IEuropean Healthcare Professional IEU-EC- 10011327207 EU-EC- 10011327207 EU-EC- 10011327207 20/01/2022 Spontaneous Non Healthcare Professional IEuropean Healthcare Professional IEU-EC- 10011327207 EU-EC- 10011327202 20/01/2022 Spontaneous Non Healthcare Professional IEU-EC- 10011327202 EU-EC- 10011327202 20/01/2022 Spontaneous Non European Healthcare Professional IEU-EC- 10011327202 EU-EC- 10011327202 20/01/2022 Spontaneous Non European Not Street N											(n/a - Not Recovered/Not			
EU-EC- 10011327207 20/01/2022 Spontaneous Non Healthcare Professional European Healthcare Professional Seconomic Area EU-EC- 10011327222 20/01/2022 Spontaneous Non Healthcare Professional Seconomic Area Non Healthcare Professional Seconomic Area Not Recovered/Resolved - (S - Immunisation - n/a - [n/a - n/a - n/a]) Not reported Seconomic Not Recovered/Not Recovered/Not Recovered/Not Resolved - (S - Immunisation - n/a - [n/a - n/a - n/a]) Not reported Seconomic Not Recovered/Not Recovered/Not Recovered/Not Resolved - (S - Immunisation - n/a - [n/a - n/a - n/a]) EU-EC- 20/01/2022 Spontaneous Non European Not Seconomic Area Not reported Seconomic Not reported Seconomic Not Pears Not Previous (n/a - Unknown -) Vomiting (n/a - Unknown -) EU-EC- 20/01/2022 Spontaneous Non European Not Seconomic Not Seconomic Area Not reported Seconomic Not reported Seconomic Not Pears Not Seconomic Not Pears Not Seconomic Not Seconomic Not Seconomic Not Seconomic Not Recovered/Not Recovere			20/01/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Headache (1d -	(S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011327222 20/01/2022 Spontaneous Non Healthcare Professional Reconomic Area Not wallable Spontaneous Non Healthcare Professional Spontaneous Non Healthcare Professional Spontaneous Non European Not Spontaneous Non Headache (1d - COMIRNATY [TOZINAMERAN] Not reported ICSR			20/01/2022	Spontaneous	Non Hea l thcare	European Economic		Child	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	<u>ICSR</u>
Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -) EU-EC- 20/01/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY [TOZINAMERAN] Not reported ICSR			20/01/2022	Spontaneous	Non Hea l thcare	European Economic		Child	Male	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
Unknown -) EU-EC- 20/01/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY [TOZINAMERAN] Not reported ICSR														
EU-EC- 20/01/2022 Spontaneous Non European Not 3-11 Child Male No Headache (1d - COMIRNATY [TOZINAMERAN] Not reported ICSR											Vomiting (n/a -			
			20/01/2022	Spontaneous				Child	Male	No	Headache (1d -		Not reported	<u>ICSR</u>

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:U-EC- .0011328068	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Fatigue (5d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Headache (3d - Recovering/Resolving -)			
U-EC- 0011328219	20/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011328483		,	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	- Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
:U-EC- .0011328528	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Fatigue (15d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
:U-EC- .0011329723	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
U-EC- .0011329744	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- .0011329820	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Headache (1d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Not Resolved -), Influenza (2d - Not Recovered/Not			
										Resolved -), Injection site pain (1d			
										- Recovered/Resolved -), Nausea (1d - Not Recovered/Not			
EU-EC- 10011329913	20/01/2022	Spontaneous	Non Hea l thcare	European Economic	Not available	3-11 Years	Child	Female	No	Resolved -) Vomiting (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICS
EU-EC- 10011330346	20/01/2022	Spontaneous	Professional Non Healthcare	Area European Economic	Not available	3-11 Years	Child	Female	No	Resolved -) Headache (0d - Recovered/Resolved -	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
EU-EC- .0011330385	20/01/2022	Spontaneous	Non Hea l thcare	Area European Economic	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -	(S - Immunisation - n/a - [n/a	Not reported	ICS
:U-EC- .0011330386	20/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
EU-EC- 10011330515	20/01/2022	Spontaneous	Professional Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (n/a - Recovered/Resolved -	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011330632	20/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011331007	20/01/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011331514	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Ecchymosis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Henoch-Schonlein purpura (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011331719	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Headache (0d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -),			
										Rash (2d - Recovered/Resolved -),			
	20/21 7		No	-	N	2.1	No.			Urticaria (2d - Recovered/Resolved -)	COMPANIE		-
EU-EC- .0011332452	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
										Pyrexia (1d -			

										Recovered/Resolved -			
EU-EC- 10011340709	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menarche (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011306441	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011306667	19/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye irritation (3d - Recovered/Resolved -), Ocular hyperaemia (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011306670	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No) Vaccination site pain (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSF
EU-EC- 10011306680	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSF
										Vaccination site pain (1d - Recovered/Resolved -	Intramuscular])		
EU-EC- 10011306690	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (0d - Recovered/Resolved -), Vertigo (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	[n/a - n/a - n/a]), [CICLOSPORIN] (C - n/a - n/a]),	
												[MYCOPHENOLATE MOFETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10011306758	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSF</u>
EU-EC- 10011306932	19/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Rash morbilliform (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[OXATOMIDE, OXATOMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10011307170	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011307173	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011310468	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - n/a])	Not reported	ICSF
EU-EC- 10011310475	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Condition) Headache (n/a - Unknown -), Hypotonia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Lymphadenopathy (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Product administered to patient of			
EU-EC- 10011312034	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	inappropriate age (n/a - Unknown -) Loss of consciousness (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a2mL - Intramuscular])	Not reported	ICSF
										Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged	-		
EU-EC- 10011312136	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hospitalisation) Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchitis (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF

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										Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011312466	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (2d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (1d - Recovering/Resolving			
EU-EC- 10011312467	19/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	,	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011312578		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011312627	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011312629	19/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011312644	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011312660	19/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	- Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314108	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye pain (n/a - Unknown -), Uveitis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314314	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314483	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Rash (3d - Not Recovered/Not Resolved -)			
EU-EC- 10011314549	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	· · · · · · · · · · · · · · · · · · ·	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011316729	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (19h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (6h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Neck pain (7h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (24h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{OF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011318518	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)			
EU-EC- 10011318839	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Swelling (n/a - Recovering/Resolving -), Tenderness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	EMEDASTINE DIFUMARATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	ICSR
										Recovering/Resolving -)		OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	
												[MICONAZOLE NITRATE, HYDROCORTISONE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]),	
EU-EC-	19/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Diarrhoea (1d -	COMIRNATY [TOZINAMERAN]	[NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral]) Not reported	ICSR
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	10011318848					available	Years				Recovered/Resolved -	Not applicable - [n/a - 1{DF}		
	EU-EC- 10011318849	19/01/2022	Spontaneous	Healthcare	Economic			Child	Male	No	Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSF
1-20											Recovering/Resolving			
E-F	EU-EC- 10011318851	19/01/2022	Spontaneous		Economic			Child	Male	No	Lymphadenitis (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	FUROATE] (C - Rhinorrhoea -	ICSR
Hef- 1807-7027 Soverance New York Professional Sourance New York Prof												ilyaj)	FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a -	
PACE													[n/a - n/a - Oral]),	
1967 1967													MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a -	
1.5 1.5													n/a - [n/a - n/a - Òral]),	
													SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	
Polytopia Professional Profess	EU-EC- 10011318868		·	Healthcare Professional	Economic Area	available	Years				Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	,	ICSR
19/01/2022 Spontamenous Healthicises Currowent Professional Suurowent Professional Profes	EU-EC- 10011318935	19/01/2022	Spontaneous		Economic			Adolescent	Male	No		(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	DIPROPIONATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - Asthma - n/a - [n/a - n/a -	ICSR
Professional Concerns Area Professional Concerns Profession													SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory	
19/01/2022 Sportameous Non	EU-EC- 10011318983	19/01/2022	Spontaneous		Economic			Child	Male	No		(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a -	ICSR
19/01/2022 Spontaneous Non Healthcare European Not Response Spontaneous Non Healthcare European Not Response Non Healthcare European Not Response Non Healthcare Spontaneous Non Healthcare European Not Response Non Healthcare Non Response Non													BETAMETHASONE DIPROPIONATE] (C - Skin disorder - n/a - [n/a - n/a -	
SUFEC 19/01/2022 Spontaneous Non European Professional Area Not Professional Area Not													- [n/a - n/a - Oral]),	
Healthcare Economic Professional Area Professional Professi													SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory	
Professional Economic Area European Healthcare Professional Professional European Healthcare Professional Professional European Healthcare Professional Area European Healthcare Professional European Healthcare Professional Area European Healthcare Professional Economic Area European Healthcare P	EU-EC- 10011318992	19/01/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Recovered/Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
Healthcare Economic Professional Pears	EU-EC- 10011318998	19/01/2022	Spontaneous		Economic			Child	Female	No	Recovered/Not	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
Healthcare Professional Profe	EU-EC- 10011319005	19/01/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Recovered/Not	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
19/01/2022 Spontaneous Non Healthcare Professional 19/01/2022 Spontaneous Healthcare Professional 19/01/2022 19/01/	EU-EC- 10011319006	19/01/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Recovered/Not	(S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
Healthcare Professional Area Individual Spontaneous Professional Successional Professional Successional Professional Successional Professional Successional Professional Successional Successional Successional Professional Successional Succ											(n/a - Not Recovered/Not			
Healthcare Professional Profess	EU-EC- 10011319032	19/01/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Recovered/Resolved -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
Professional Economic Area available Years Unknown -) (S - COVID-19 immunisation - FUROATE] (C - Rhinorrhoea - n/a - 1{DF} - n/a])	EU-EC- 10011319033	19/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Female	No	Recovered/Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
Professional Economic Area available Years Unknown -), Unknown -), (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) EU-EC- 0011319199 Professional Professional Realthcare Professional Area Professional Professi	EU-EC- 10011319035	19/01/2022	Spontaneous		Economic			Adolescent	Female	No		(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	FUROATE] (C - Rhinorrhoea -	ICSR
Unknown -), Vomiting (n/a - Unknown -) Vomiting (n/a - Unknown -), Vomiting (n/a - Unknown -)	EU-EC- 10011319167	19/01/2022	Spontaneous		Economic			Child	Male	No	Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSF
U-EC- .0011319199 Spontaneous Healthcare Professional Professional Real Healthcare Professional Real Healthcare Professional Reconomic Area Spontaneous Real Healthcare Professional Reconomic Area Spontaneous Real Healthcare Professional Reconomic Reconomic Area Spontaneous Real Healthcare Professional Reconomic Reconomic Real Real Real Real Real Real Real Real											Unknown -),			
0011319199 Professional Economic Area Professional Economic Unknown -), (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}} Vomiting (n/a - Unknown -)	EU EC	10/01/255	Const.	1112	 	Net	2.11	Chil	F :	l.	Unknown -)	COMPNIATIVITOTE	Not assessed	100
Unknown -)	EU-EC- 10011319199	19/01/2022	Spontaneous		Economic			Child	remale	No	Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
	EU-EC-	19/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	· · · · · · · · · · · · · · · · · · ·	 COMIRNATY [TOZINAMERAN]	Not reported	ICSR

30.11.2022 (03.53							R	tun Lii	ne Listing Report			
10011319237			Professional	Economic Area	available	Years				erythema (n/a - Unknown -), Vaccination site warmth (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10011320330	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Unknown -) Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10011293263	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Important Condition) Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011293317	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -), Vaccination site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC- 10011293525	18/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Not	Ma l e	No	Recovered/Resolved -) Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC-	18/01/2022	Spontaneous		Area	Not	3-11	Specified Not	Male	No	(n/a - Recovered/Resolved -) Initial insomnia (n/a -	Not applicable - [n/a - 10ug - Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011293547	16/01/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Specified	Male	No	Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICOK
										Middle insomnia (n/a - Not Recovered/Not Resolved -),			
										Nightmare (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011293962	18/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bone pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10011294146	18/01/2022	Spontaneous	Non Healthcare Professional	l .	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
										Agitation (n/a - Recovered/Resolved -), Irritability (n/a -			
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	3-11	Not	Male	No	Recovered/Resolved -) Abnormal behaviour	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011294147	10/01/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Specified	ridic	NO	(n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	not reported	ICSIN
										Agitation (n/a - Recovered/Resolved -),			
										Irritability (n/a - Recovered/Resolved -)			
EU-EC- 10011296347	18/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011300364	18/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Chest pain (1d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011300558	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hospitalisation) Chillblains (2d - Recovered/Resolved - Other Medically	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	[LANSOPRAZOLE] (C - n/a - n/a -),	ICSR
				Aled						Important Condition), Ill-defined disorder (2d -	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a -),	
										Recovered/Resolved - Other Medically Important Condition)	арупсаше - [пуа - пуа - пуа])	[POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350]	
												(C - n/a - n/a -), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL	
EU-EC- 10011301042	18/01/2022	Spontaneous	Non Hea l thcare	Non European	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	SULFATE] (C - n/a - n/a -) Not reported	ICSR

0.11.2022	03.03							K	ull Lii	ie Listing Report			
			Professional	Economic Area			·			Bell's palsy (n/a - Unknown - Other Medically Important Condition),	19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Hypoaesthesia (n/a - Unknown -), Illness (n/a -			
										Unknown -)			
EU-EC- 10011301564	18/01/2022	Spontaneous			Not available	3-11 Years	Not Specified	Male	No	Malaise (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Myalgia (1d - Recovered/Resolved -)			
EU-EC- 10011301776	18/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Feeling hot (10min - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	Not reported	ICSR
										Hyperhidrosis (10min - Recovered/Resolved -), Pallor (10min -	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Tinnitus (10min -			
										Recovered/Resolved -), Vision blurred (10min			
EU-EC-	18/01/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	- Recovered/Resolved -) Chest pain (n/a - Not	TOZINAMERAN	Not reported	ICSR
10011301926			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved -), Dyspnoea (n/a - Not	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])		
										Recovered/Not Resolved -),			
										Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011302299	18/01/2022	Spontaneous	Healthcare Professional			3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR
										Arthralgia (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Petechiae (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011302563		Spontaneous	Healthcare Professional	Area	Not available	3-11 Years	Not Specified	Female	No	Immunisation reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10011302635	18/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Angioedema (n/a - Recovering/Resolving -),			
										Decreased appetite (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011304041	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU = 2	10/04 (200		No	5	Net		Child		N.	Drug ineffective (n/a - Unknown - Other Medically Important Condition)	-		100
EU-EC- 10011304530	18/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Female	No	Oropharyngeal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a -			

		I	I				1			Recovering/Resolving	1	[
EU-EC- 10011304531	18/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	[AMOXICILLIN] (C - n/a - Unknown -),	ICSR
			Professional	Area						(n/a - Not Recovered/Not Resolved -)	Drug withdrawn - [1d - n/a - Intramuscular])	[IBUPROFEN] (C - n/a - Unknown -),	
												[PARACETAMOL] (C - n/a - Unknown -)	
EU-EC- 10011304537	18/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Streptococcal infection - Drug withdrawn - [11d - 250mg - Oral])	
										Pyrexia (n/a - Not Recovered/Not Resolved -)		[
EU-EC- 10011304539	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011304542	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	FALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND	ICSF
												3] (C - Immunisation - Drug withdrawn - [1d - n/a - n/a])	
EU-EC- 10011304549	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Ma l e	No	Vaccination site inflammation (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Vaccination site rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011304551	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pain (n/a - Recovering/Resolving -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										lymphadenopathy (n/a - Recovering/Resolving			
EU-EC- 10011305350	18/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Condition aggravated (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Tic (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011305402	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Injection site pain (0d - Recovering/Resolving -),			
										Paraesthesia (0d - Recovered/Resolved -),			
										Pruritus (0d - Recovered/Resolved -),			
										Vaccination site pain (0d - Recovering/Resolving			
EU-EC- 10011305441	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Granuloma annulare (13d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011305442	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Ma l e	No	Angioedema (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSR
										Erythema (n/a - Recovering/Resolving -),			
	10/5: 77						lau II :			Pruritus (n/a - Recovering/Resolving			
EU-EC- 10011305475	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (0d - Recovered/Resolved -), Palpitations (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-	18/01/2022	Spontaneous		Non	Not	3-11	Not	Female	No	Recovered/Resolved -) Drug ineffective (n/a -	TOZINAMERAN	Not reported	ICSR
10011306004		,	Healthcare Professional	European	available	Years	Specified			Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
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30.11.2022	30.00							- 1	uii Lii	ie Listing Report			
EU-EC- 10011283005	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Child	Male	No	Syncope (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Tremor (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011283256	17/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Bronchial wall thickening (n/a - Unknown -),	Intramuscular])		
										Fatigue (n/a - Unknown -),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Pallor (n/a - Not Recovered/Not Resolved -),			
										Somnolence (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011283496		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	·	ICSR
EU-EC- 10011284557	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Injection site pain (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Rash (1d - Not Recovered/Not Resolved -)			
EU-EC- 10011284620	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011284651	17/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (3d - Recovering/Resolving -),			
										Nausea (1d - Recovering/Resolving -),			
										Nausea (2d - Recovering/Resolving -),			
										Vomiting (0d - Recovering/Resolving -)			
EU-EC- 10011284675	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011286858	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cold sweat (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Confusional state (n/a - Not Recovered/Not Resolved -),			
										Dizziness (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Feeling abnormal (n/a - Not Recovered/Not Resolved -),			
										Feeling hot (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011288289	17/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (2d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - .05mg - Oral]),	ICSR
										Headache (2d - Recovered/Resolved -),		[OXCARBAZEPINE] (C - Seizure - n/a - [n/a - 14mL - Oral])	
										Pyrexia (n/a - Unknown -),			
										Tardive dyskinesia (n/a - Not Recovered/Not Resolved - Other			

J. 11.2022 C	J3.53								un Lii	ne Listing Report			
										Medically Important Condition)			
EU-EC- 10011288491	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactoid reaction (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011289539	17/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Intermenstrual bleeding (n/a - Recovering/Resolving -), Premenstrual syndrome (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d2mL - Intramuscular])	Not reported	ICS
EU-EC- 10011289567	17/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	-) Erythema nodosum (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
EU-EC- 10011290319	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Parosmia (n/a - Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[LEVOCETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 5mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Hypersensitivity - n/a - [n/a - 5mg - Oral])	ICS
EU-EC- 10011291879	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Recovered/Not Resolved -) Eczema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICS
EU-EC- 10011291902	17/01/2022	Spontaneous	Non Hea l thcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstruation irregular (5d - Recovered/Resolved -	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICS
EU-EC- 10011291947	17/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Other Medically Important Condition)	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011291967	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011292179	17/01/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	(n/a - Not Recovered/Not Resolved -) Febrile convulsion (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
				Area	available					- Caused/Prolonged Hospitalisation)	Not applicable - [1d2mL - Intramuscular])		
EU-EC- 10011277832	15/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Pruritus (0d - Recovered/Resolved -), Urticaria (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011278106	15/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011278227	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tachypnoea (1d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[FLUTICASONE PROPIONATE] (C - Bronchospasm - n/a - [n/a - 1{DF} - Respiratory (inhalation)])	
										Wheezing (1d - Recovered/Resolved -			
EU-EC- 10011278231	15/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eczema nummular (n/a - Recovering/Resolving -), Oedema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Skin reaction (n/a - Recovering/Resolving			
EU-EC- 10011278278	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site oedema (n/a - Unknown -), Oedema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
		Spontaneous		European	Not	3-11	Not	Male	No	Unknown -) Injection site pain (2d	COMIRNATY [TOZINAMERAN]	Not reported	ICS

										Recovering/Resolving	1	1	
EU-EC- 10011262515	14/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Professional								Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10011262637	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICS
										Dyspnoea (n/a - Not Recovered/Not Resolved -),	and an assessment j		
										Respiratory fatigue (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011262755	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICS
										Vertigo (n/a - Recovered/Resolved -),	- Intramuscular])		
										Vomiting (n/a - Recovered/Resolved -			
EU-EC- 10011262766	14/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICS
FU 50	14/04/2022					2.11				Pyrexia (n/a - Unknown -)	Intramuscular])		100
EU-EC- 10011262768	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nausea (n/a - Unknown -), Retching (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Unknown -), Vomiting (n/a - Unknown -)			
EU-EC- 10011262992	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site vesicles (8d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011263785	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICS
EU-EC- 10011264475	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a -	Not reported	ICS
										Asthenia (n/a - Recovering/Resolving -),	Subcutaneous])		
										Chills (n/a - Recovering/Resolving -),			
										Diarrhoea (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011264714	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (2d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	LEVETIRACETAM [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 500mg - Oral])	ICS
										Disease recurrence (n/a - Unknown - Other Medically Important Condition),			
										Headache (2d - Recovered/Resolved -),			
										Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011266685	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Ma l e	No	Injection site pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011266853	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (0d - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011267825	14/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Hospitalisation) COVID-19 (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICS
				Area						Condition), Drug ineffective (n/a - Unknown - Other	applicable - [1d - n/a - n/a])		

										Medically Important Condition)			
EU-EC- 10011267865	14/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No		TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - .05mg - Oral]),	ICS
										Headache (2d - Recovered/Resolved -),		[OXCARBAZEPINE] (C - Seizure - n/a - [n/a - 14mL - Oral])	
										Tardive dyskinesia (n/a - Unknown - Other Medically Important Condition)			
:U-EC- .0011268165	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Autoimmune disorder (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Rash (n/a - Not Recovered/Not Resolved -)			
:U-EC- 0011268983	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypotonia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC
										Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (725min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011273061	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	IC
										Migraine (5d - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10011273477	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL -	Not reported	10
EU-EC- 10011274479	14/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ataxia (n/a - Not Recovered/Not Resolved -),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
										Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
										Condition), Speech disorder (n/a			
										- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011275254	14/01/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown -), Decreased appetite	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[BACILLUS COAGULANS] (C - n/a - n/a - [n/a - n/a - n/a])	IC
				Aica						(n/a - Unknown -), Disorientation (n/a -	аррисаме [п/а п/а п/а])		
										Recovered/Resolved -			
										Feeling hot (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Visual impairment (n/a - Recovered/Resolved -			

										Nausea (n/a -	Intramuscular])		
EU-EC- 10011276317	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Female	No	Recovered/Not Resolved -) Diarrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a -	Not reported	ICS
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not			
			Professional	Area						Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10011276305	14/01/2022	Spontaneous	Healthcare	Economic	Not available	3-11 Years	Child	Female	No	Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	VACCINE H5N1 BAXTER [A/VIETNAM/1203/2004 (H5N1)] (C - Influenza immunisation - Drug withdrawn - [1d - n/a - n/a])	ICS
												NEISSERIA MENINGITIDIS GROUP Y POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN] (C - n/a - Drug withdrawn - [1d - n/a - n/a]), PANDEMIC INFLUENZA	
												NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN,	
EU-EC- 10011276034	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area		3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)		SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [N. MENINGITIDIS GROUP C (STRAID (11) POLYSACCHARIDE (DE-O-ACETYLATED) CONJUGATED TO TETANUS TOXOID,	ICS
EU-EC- 10011276010	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		ICS
										Nausea (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10011276002	14/01/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Child	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a -	Not reported	ICS
EU-EC- 10011276000	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Resolved -) Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a -	Not reported	ICS
										Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not			
										Recovered/Not Resolved -), Pyrexia (n/a - Not			
EU-EC- 10011275905	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
-11.50	1.4/01/2022		Non	<u></u>	N-4	2.11	Child	M-1-	N	Tremor (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]		Too
EU-EC- 10011275902	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011275877	14/01/2022	Spontaneous	Healthcare		Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011275865	14/01/2022	Spontaneous	Healthcare		Not available	3-11 Years	Child	Female	No	Vaccination site pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011275861	14/01/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Vaccination site bruising (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011275841	14/01/2022	Spontaneous			Not available	3-11 Years	Child	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
				Area						Not Recovered/Not Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		

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										Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving			
:U-EC- 0011276358	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (1d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	[BUDESONIDE] (C - Asthma - Dose not changed - [n/a - 200ug - Respiratory (inhalation)])	IC
:U-EC- 0011277027	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hospitalisation) Chills (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	IC
:U-EC- .0011277468	14/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Adult	Female	No	Vomiting (1d - Recovered/Resolved -) Chest discomfort (37d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
			Professional			, cans				Recovering/Resolving -), Influenza like illness (37d - Recovering/Resolving -)	- n/a - Intramuscular])		
EU-EC- .0011247330	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011247470	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site reaction (n/a - Not Recovered/Not Resolved -)	(S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011247513	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC-	12/01/2022	Casatanasus	Llookh sava		Not	3-11	Not	Male	No	Pyrexia (n/a - Unknown -) Urticaria (15d -	COMIRNATY [TOZINAMERAN]	METHOTREVATE	TCC
10011247580		Spontaneous	Professional	Area	available	Years	Not Specified			Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[METHOTREXATE] (C - n/a - n/a - [n/a - 10ug - n/a])	ICS
EU-EC- 10011247674	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICS
EU-EC- 10011249129	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (42d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Headache (68d - Not Recovered/Not Resolved -)			
EU-EC- 10011249335		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICS
EU-EC- 10011250238	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Product administered to patient of inappropriate age (n/a - Unknown -),			
EU-EC-	12/01/2022	Chortex	Non	Non	Not	3-11	Not	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition) Loss of consciousness	TOZINAMEDAN	TA/HONG KONG/4004 (2014	TOT
10011250240	13/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Specified	Tendle	INU	(n/a - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD	
										Pallor (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -		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)	
										Vomiting (n/a - Recovered/Resolved -),		(H3N2)-LIKE STRAIN (A/HON KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN	٩G

30.11.2022	03.03							K	Kull Lii	ie Listing Report			
										Yellow skin (n/a - Recovered/Resolved -)		(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)P0M09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [1d - n/a - n/a])	
EU-EC- 10011250290	13/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blindness (5min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Fatigue (n/a - Unknown -),			
										Hyperhidrosis (n/a - Unknown -),			
										Mydriasis (5min - Recovered/Resolved -),			
										Pallor (n/a - Unknown -),			
										Presyncope (n/a - Recovered/Resolved -),			
EU EC	12/01/2022	Cnontanaous	Non	Non	Not	2 11	Not	Fomale	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
EU-EC- 10011251733	13/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	INO	COVID-19 (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011253410	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vomiting (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011253685	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination site swelling (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011253841	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011255650	13/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (8h - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
511.50	12/01/200									Recovered/Resolved - Other Medically Important Condition)	Intramuscular])		1000
EU-EC- 10011255683	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011256993	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Administration site pain (4d - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[n/a - 5mg - n/a]), [METHOTREXATE] (C - n/a -	ICSR
										Important Condition), Constipation (4d - Recovering/Resolving - Other Medically Important Condition),		n/a - [n/a - 10mg - n/a]), [METHOTREXATE] (C - n/a - n/a - [n/a - 2.5mg - n/a])	
										Decreased appetite (4d - Recovering/Resolving - Other Medically Important Condition),			
										Haematochezia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Mucous stools (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (4d - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011257103	13/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Alopecia areata (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Inflammation (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10011260307	13/01/2022	Spontaneous	Non Healthcare	Non European	Not available	3-11 Years	Not Specified	Female	No	Disability (n/a - Unknown - Disabling,	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

			Professional	Economic Area						Other Medically Important Condition)	19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011260844	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (5h - Recovered/Resolved -), Vomiting (5h -	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Recovered/Resolved -)			
EU-EC- 10011261143	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
U-EC- 1.0011261144	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	IC
EU-EC- 10011261150	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])		IC
EU-EC- 10011261166	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site hypersensitivity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	IC
EU-EC- 10011261173	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	IC
										Rash (n/a - Recovering/Resolving -)			
EU-EC- 10011261177	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Dyskinesia (n/a - Recovering/Resolving -), Tic (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	<u>IC</u>
10011261192		Spontaneous	Professional	European Area European	Not available	3-11 Years	Child	Male	No	Epistaxis (0d - Recovered/Resolved -), Ocular hyperaemia (0d - Recovered/Resolved -) Pruritus (4d -	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[BETAMETHASONE VALERATE, FUSIDIC ACID, BETAMETHASONE VALERATE, FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE, ANHYDROUS FUSIDIC ACID, BETAMETHASONE, FUSIDIC ACID, BETAMETHASONE, FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE, FUSIDIC ACID PH. EUR., FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE VALERATE (PH. EUR.), FUSIDIC ACID, BETAMETHASONE] (C Eczema infected - n/a - [n/a - n/a - Cutaneous]), [HYDROCORTISONE BUTYRATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous])	
0011261198	15/01/2022	Spontaneous	Professional		available	Years	Cind	remale	NO	Recovered/Resolved -), Urticaria (4d - Recovered/Resolved -)	(S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	(C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [HYDROCORTISONE BUTYRATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC- 10011261200	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -), Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	10
EU-EC- 10011261209	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
EU-EC- 10011261215	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Decreased appetite (n/a - Unknown -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	IC
	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a)	Not reported	<u>I(</u>
EU-EC- 10011261222						1	1	1		1	- ii/a] <i>)</i>		IC

		I		l		1	I	I	I	Recovering/Resolving			
EU-EC-	13/01/2022	Spontaneous		European	Not	3-11	Child	Female	No	-) Discomfort (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
.0011261256			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -),	(S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]),		
										General physical condition abnormal (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}		
										Malaise (n/a - Unknown -),	- n/a])		
										Pain in extremity (n/a - Unknown -),			
										Restlessness (n/a - Recovering/Resolving -)			
EU-EC- 10011261261	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		ICSR
												[EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - Intramuscular]),	
												[HYDROCORTISONE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	
												[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Pharyngitis - n/a - [n/a - n/a - Oral]),	
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory	
EU-EC- 10011261566	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Feeling abnormal (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	(inhalation)]) Not reported	ICSR
										Paraesthesia (n/a - Not Recovered/Not Resolved -)	- n/a])		
EU-EC- 10011261567	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
										Vomiting (n/a - Not Recovered/Not Resolved -)	n/a])		
EU-EC- 10011261576	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Lip erythema (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
										Rash erythematous (1d - Recovered/Resolved -),	.,,,,,		
										Swelling (1d - Recovered/Resolved -			
EU-EC- 10011261579	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pruritus (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Restlessness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Urticaria (n/a - Unknown - Life Threatening, Caused/Prolonged			
EU-EC-	13/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Hospitalisation) Contusion (n/a -	 COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011261595			Professional	Economic Area	available	Years				Unknown - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
										Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011261598	13/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved -),	- 11/4])		
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Tremor (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10011261671	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011261672	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		ICSR
												[SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]),	
												[SOLIFENACIN, SOLIFENACIN SUCCINATE] (C - Incontinence - n/a - [n/a - n/a - Oral]),	
												[TERBUTALINE SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	
EU-EC- 10011261676	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		ICSR
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011261677	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Axillary pain (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Sensory disturbance (n/a - Recovering/Resolving			
EU-EC- 10011261688	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -		
										Nausea (n/a - Not Recovered/Not Resolved -),	Not applicable - [n/a - 1{DF} - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011261691	13/01/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1.5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Nausea (1d - Recovered/Resolved -),	, 1, ~, 1		
										Pyrexia (1.5d - Recovered/Resolved -),			
										Vomiting (1.5d - Recovered/Resolved -)			
EU-EC-	13/01/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Female	No	Chills (1d -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10011261695			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10011261697	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Aphonia (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011261702	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (4d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10011261732	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
EU-EC- 10011261735	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011261737	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011261739	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Dyspnoea (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011261746	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Lip swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011261759	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011261762	13/01/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	I	ICSR
										Nessived)		[n/a - n/a - Respiratory (inhalation)]), [MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm -	
EU-EC-	13/01/2022	Spontaneous	Non	Furonean	Not	3-11	Child	Female	No	Vaccination site	COMIDNATY [TOZINAMEDAN]	n/a - [n/a - n/a - Respiratory (inhalation)]) Not reported	ICSR
10011261763			Healthcare Professional		available	Years				granuloma (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	'	
EU-EC- 10011261764	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Pyrexia (1d - Recovered/Resolved -			
EU-EC-	10/04/0000	Spontaneous	Non	European	Not	3-11	Child	Female	No	Herpes zoster (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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