Line Listing Report Time run: 30/11/2022 03:16:53

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10012316617	27/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Injection site irritation (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL -	Not reported	ICSR
EU-EC- 10012319503	27/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Dengue virus test positive (n/a - Unknown -), Fatigue (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Mental status changes (n/a - Unknown -), Platelet count decreased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
FILES	27/04/2022					2.44	0.71			Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			1000
EU-EC- 10012320195	27/04/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Unknown -), Vaccination site lymphadenopathy (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
										Vaccination site pain (n/a - Unknown -)			
EU-EC- 10012321047	27/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (70d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012321131	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Allergic oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
										Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
										Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012321138	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Chi l d	Female	No	Ascites (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Cardiac failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Multisystem inflammatory syndrome in children (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10012321150	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Appendicectomy (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Appendicitis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012321177		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012299782	26/04/2022 	Spontaneous	Professional	Non European	Not available	3-11 Years	Not Specified	Female	No	Nausea (7d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF

				Economic Area						- Other Medically Important Condition)	Not applicable - [n/a - n/a -		
EU-EC- 10012299784	26/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
EU-EC- 10012300704	26/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
EU-EC- 10012301798	26/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Syncope (n/a -	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10012301850	26/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved - Other Medically Important Condition) Dizziness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC-	26/04/2022	Spontaneous		Non	Not	3-11	Not	Male	No	Condition), Pallor (n/a - Unknown - Other Medically Important Condition) Seizure (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10012301936 EU-EC- 10012301980	26/04/2022	Spontaneous	Professional Healthcare Professional	European Economic Area Non European	available Not available	Years 3-11 Years	Specified Not Specified	Male	No	Recovered/Resolved - Other Medically Important Condition) Appendicitis perforated (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
EU-EC- 10012302220	26/04/2022	Spontaneous		Economic Area European Economic	Not available	3-11 Years	Elderly	Female	No	Recovering/Resolving - Other Medically Important Condition) Influenza (25d - Not Recovered/Not		Not reported	ICS
EU-EC- 10012302535	26/04/2022	Spontaneous	Professional	Area Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Resolved -) Cyanosis (1d - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a -	(S Infindingation 17)a - [tiya - n/a - Subcutaneous]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Recovering/Resolving - Other Medically Important Condition), Pallor (1d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Visual impairment			
										(n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012302793	26/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Epistaxis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
D-EC-		Spontaneous			Not	3-11	Not	Female	No	Abdominal pain	COMIRNATY [TOZINAMERAN]	Not reported	IC:

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10012302915			Professional	European Economic Area	available	Years	Specified			upper (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Diarrhoea (n/a - Recovered/Resolved -),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012303046	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Unknown -),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012303050	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Myalgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved -)			
EU-EC- 10012303295	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hyperacusis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012303728	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Vaccine breakthrough infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012304317	26/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Glycosylated haemoglobin increased (n/a - Unknown - Life Threatening, Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

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										Hospitalisation, Disabling, Other Medically Important Condition),			
										Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10012304846	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012305098	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Cough (n/a - Recovered/Resolved -), Dyspnoea (n/a -			
										Recovered/Resolved -), Myocarditis (n/a -			
										Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Tachypnoea (n/a - Recovered/Resolved -),			
										Troponin increased (n/a - Recovered/Resolved -)			
EU-EC- 10012305133	26/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Eye swelling (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Swelling face (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012305473	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nephritis (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- 10012305580	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dengue virus test positive (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Urine analysis abnormal (n/a - Unknown -)			
EU-EC- 10012305801	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cardiac murmur (8d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (1d - Recovered/Resolved -),			
										Headache (37h - Recovered/Resolved -),			
										Pulmonary valve incompetence (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (37h - Recovered/Resolved -),			
										Vomiting (n/a - Recovering/Resolving			

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										-), White blood cell count decreased (8d			
										Recovered/Resolved			
EU-EC- 10012307006	26/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (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	ICSF
EU-EC- 10012307083	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Feeling cold (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Recovered/Resolved -), Inappropriate schedule of product			
										administration (n/a - Unknown -), Musculoskeletal chest pain (n/a - Recovered/Resolved			
										-), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012308028	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -), Back pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Unknown -), Bell's palsy (n/a - Unknown - Other Medically Important			
										Condition), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			
										Condition), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dysphagia (n/a - Recovering/Resolving -),			
										Dysphonia (n/a - Unknown -),			
										Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fall (n/a - Unknown -			
										Gait disturbance (n/a - Unknown -),			
										Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Unknown -),			
										Muscle strain (n/a - Unknown -),			
										Muscular weakness (n/a - Unknown -),			
										Urinary tract infection (n/a - Unknown -),			
										Vision blurred (n/a - Unknown -), Vomiting (n/a -			
EU-EC-	26/04/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Recovering/Resolving -) Dermatitis (n/a -	COMIRNATY [TOZINAMERAN]	[IBUPROFEN] (C -	ICSF
10012308538	_0,0 1,2022	Sportaineous	Healthcare Professional	Economic	available	Years	Sind	, smale	1.40	Recovering/Resolving -), Vaccination site	(S - COVID-19 immunisation - Drug withdrawn - [1d2mL - Intramuscular])	Odynophagia - Drug withdrawn - [7d - 400mg - n/a])	1000

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										(n/a - Recovering/Resolving			
EU-EC- 10012308852	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Headache (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Platelet count decreased (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012309370	26/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (66h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Rash (66h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012309475	26/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lid sulcus deepened (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Mucosal dryness (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012309486	26/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012309548	26/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (135min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Headache (135min - Recovered/Resolved -),			
										Loss of consciousness (135min - Recovered/Resolved - Other Medically			
EU-EC- 10012289786	25/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Important Condition) Accidental overdose (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICS
										Injection site pain (n/a - Unknown -),			
										Product administration error (n/a - Unknown -)			
EU-EC- 10012290512	25/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICS
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
										Seizure (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012290611	25/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICS

											MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10012290654	25/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eczema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10012290779	25/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Discomfort (n/a - Recovering/Resolving -), Febrile convulsion	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										(n/a - Recovering/Resolving -), Muscle spasms (n/a -			
										Recovering/Resolving -), Parotid gland			
										enlargement (n/a - Recovered/Resolved -),			
										Parotid gland enlargement (n/a - Unknown -), Parotitis (n/a -			
										Recovering/Resolving -), Pyrexia (n/a -			
										Recovering/Resolving -), Seizure (n/a -			
	25/04/2022	Spontaneous		Non	Not	3-11	Not	Female	No	Recovering/Resolving - Other Medically Important Condition) Blood phosphorus	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10012290801			Healthcare Professional	European Economic Area	available	Years	Specified			decreased (n/a - Not Recovered/Not Resolved -), Serum ferritin	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										increased (n/a - Not Recovered/Not Resolved -),			
										Weight decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012291284	25/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Torticollis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10012291929	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Elderly	Female	No	Musculoskeletal pain (153d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICS</u> I
EU-EC- 10012292715	25/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (8h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Erythema (8h - Recovered/Resolved -), Pain (8h -			
										Recovered/Resolved -), Pruritus (8h -			
EU-EC-	25/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Recovered/Resolved -) Diarrhoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10012293012	25, 6 1, 2622	эролатова	Healthcare Professional	Economic	available	Years	Specified	, emale			(S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Тесторогея	100.
EU-EC- 10012295743	25/04/2022	Spontaneous	Healthcare	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 -	Not reported	ICSI
EU-EC- 10012295752	25/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cough (n/a - Unknown -),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSI
										Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -)	Intramuscular])		
EU-EC- 10012296096	25/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperthermia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10012296678	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain lower (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMINATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSI
		Spontaneous			Not	3-11	Child	Female	No	Headache (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSI

										ie Listing Repor			
										Hospitalisation), Sleep disorder (n/a - Unknown -			
										Caused/Prolonged Hospitalisation)			
EU-EC- 10012297363	25/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012297413	25/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Headache (n/a - Unknown - Disabling),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	
EU EO	24/04/2022		No.	No		2.44		M. I.		Ocular discomfort (n/a - Unknown - Disabling)	COMPANY (TOTAL MEDIA)		1000
EU-EC- 10012287177	24/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012273932	22/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC-	22/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Pyrexia (n/a - Recovered/Resolved -) Myalgia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012273933	22,04,2022	Sportaneous	Healthcare	Economic Area	available	Years	Specified	remaie		Recovered/Resolved -), Somnolence (n/a - Recovered/Resolved	(S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSIN
EU-EC- 10012273961	22/04/2022	Spontaneous		European Economic	Not available	3-11 Years	Not Specified	Male	No	-) Vertigo (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10012273965	22/04/2022	Spontaneous	Healthcare	Area European Economic	Not available	3-11 Years	Not Specified	Male	No	-) Agitation (n/a - Recovering/Resolving	n/a - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						-), Vertigo (n/a - Recovering/Resolving -)	n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012273967	22/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273968	22/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273975	22/04/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Female	No	Erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273981	22/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Unknown -), Presyncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273983	22/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Presyncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273985	22/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012273986	22/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Erythema (n/a - Unknown -), Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012273988	22/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Muscular weakness (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -), Rash (n/a -			
EU-EC-	22/04/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Recovered/Resolved -) Immune system	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012275124				European Economic Area	available	Years	Specified			disorder (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		- 551
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Tonsillar hypertrophy (n/a - Unknown - Other Medically Important Condition)			

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EU-EC- 10012276469	22/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	<u>ICSR</u>
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012276876	22/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Langerhans' cell histiocytosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012277147	22/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	Yes	Ataxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Facial paresis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mg - n/a])	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation, Disabling), IIIrd nerve paresis (n/a - Unknown -			
										Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10012279007		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012279448	22/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypersensitivity (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012280978	22/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10012282009	22/04/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Cough (n/a - Fatal - Results in Death),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Dyspnoea (n/a - Fatal - Results in Death),	Intramuscular])		
										Headache (n/a - Fatal - Results in Death),			
										Nasopharyngitis (n/a - Fatal - Results in Death),			
EU-EC- 10012282481	22/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Pyrexia (n/a - Fatal - Results in Death) Anaphylactic reaction (20min - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
										Dyspnoea (20min - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Face oedema (20min - Recovering/Resolving - Life Threatening, Caused/Prolonged			
										Hospitalisation), Hyperhidrosis (20min			
										Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Lip oedema (20min - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Periorbital oedema (20min - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10012282737	22/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Heart rate decreased (n/a - Recovered/Resolved -),			
										Hyperhidrosis (0d -			

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											Recovered/Resolved - Other Medically Important Condition),			
											Pain (n/a - Recovered/Resolved -),			
											Presyncope (0d - Recovered/Resolved - Other Medically Important Condition),			
											Seizure (0d - Recovered/Resolved - Other Medically Important Condition),			
											Transient ischaemic attack (0d - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10012283358	22/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Generalised tonic-	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											clonic seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	77-57		
											SARS-CoV-2 antibody test positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10012262926	21/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Male	No	Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
	EU-EC- 10012265299	21/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blood pressure decreased (20min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Depressed level of consciousness (20min - Recovered/Resolved - Other Medically Important Condition),			
											Heart rate decreased (20min - Recovered/Resolved -),			
											Pallor (20min - Recovered/Resolved -),			
											Presyncope (20min - Recovered/Resolved -),			
											Seizure (20min - Recovered/Resolved - Other Medically Important Condition),			
											Supine position (20min - Recovered/Resolved -)			
	EU-EC- 10012265590	21/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Cough (n/a - Recovering/Resolving -),			
											Diarrhoea (n/a - Recovering/Resolving -),			
											Pyrexia (n/a - Recovering/Resolving -),			
											Rhinorrhoea (n/a - Recovering/Resolving -),			
	EU-EC-	21/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Vomiting (n/a - Recovering/Resolving -) Urticaria (5d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10012267730			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
	EU-EC-	21/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Pruritus (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10012267767			Healthcare Professional	Economic Area	available	Years				Unknown -), Rash (n/a - Unknown -),	(S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
										Swelling face (n/a -			
EU-EC-	21/04/2022	Spontaneous			Not	3-11	Child	Female	No	Unknown -) Psoriasis (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012269108	24 /0 4 /2022		Professional	Area	available	Years	01:11			Recovered/Not Resolved -)	(S - Immunisation - n/a - [n/a - 1{DF} - n/a])		1000
EU-EC- 10012269204	21/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Asthenia (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Fatigue (0d - Recovering/Resolving -),			
										Influenza like illness (0d - Recovering/Resolving			
										-), Malaise (0d - Recovering/Resolving			
										-), Pyrexia (0d - Recovering/Resolving			
EU-EC- 10012269572	21/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Insomnia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10012270069	21/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anaphylactic reaction (470min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ULMUS SCABRA POLLEN] (C - Seasonal allergy - n/a - [n/a - n/a - Sublingual])	ICSR
										Gastrooesophageal reflux disease (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Sneezing (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012271111	21/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Female	No	Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Neck pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pharyngeal erythema (n/a - Recovering/Resolving - Other Medically			

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										Important Condition), Pharyngeal inflammation (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Sinusitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU FG	21/04/2022	Constant	Neg	5	Niek	2.11	Child	Mala	N-	Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)		Newsand	ICCD
EU-EC- 10012272192	21/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										-), Diarrhoea (n/a - Recovered/Resolved -),			
										Fatigue (n/a - Recovered/Resolved -)			
EU-EC- 10012272699	21/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (3d - Recovered/Resolved -), Vomiting (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSR
EU-EC-	20/04/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Female	No	Recovered/Resolved -) Multisystem	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012251432			Professional	Economic Area	available	Years	Specified			inflammatory syndrome in children (n/a - Recovering/Resolving - Life Threatening),	(S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])		
										Myocarditis (n/a - Recovering/Resolving - Life Threatening),			
										Pyrexia (n/a - Recovering/Resolving - Life Threatening),			
										Rash (n/a - Recovering/Resolving - Life Threatening)			
EU-EC- 10012253943	20/04/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified		No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pallor (n/a - Recovered/Resolved -),			
										Urinary incontinence (n/a - Recovered/Resolved			
EU-EC- 10012254976	20/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										SARS-CoV-2 test positive (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccine breakthrough infection (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012255096	20/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU EC	20/04/2022	Cnart-	Haalii	Ner	Niek	2.11	Net	Farra!	Me	Recovering/Resolving -)	COMIDNATY (TOZYNINGS	Not you gute 1	Icco
EU-EC- 10012255768	20/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	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	ICSR

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MACC 10072751975 20047002 Sportmonace Incating care Service Se											- Unknown - Other Medically Important			
Ex-FC 20/04/202 Southweek Preference No. More											Recovered/Resolved			
Part			Spontaneous		European Economic				Male	No	Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
Secure cellulux Secure cel			Spontaneous		Non European Economic				Male	No	Conjunctival haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
Bu-ec: 2004/2002 Spontaneous Non- Indicators 2004/2002 Spontaneous Non- Indicators											Recovered/Not			
EL-EC- 101.2259498 20/64/2022 Sporteneous Poet Po											Recovered/Not			
ELFC 20/04/2022 Sportaneous Not Professional Not Professio											Recovered/Not			
Heathcare Economic Professional Professiona	FII-FC-	20/04/2022	Spontaneous	Non	Furonean	Not	3-11	Elderly	Female	No	Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN)	Not reported	ICSR
Heathcare Economic Professorial Professo			Spontaneous	Healthcare	Economic			Liderly	remale		Recovered/Not	(S - Immunisation - n/a - [n/a	Not reported	ICSIX
ELEC. 10012258737 ELEC. 10012258737 ELEC. 10012258737 ELEC. 10012258838 ELEC. 1001258838 ELEC. 10012258838 ELEC. 10012258			Spontaneous	Healthcare	Economic			Adult	Female	No	(n/a - Not Recovered/Not Resolved - Caused/Prolonged	(S - Immunisation - n/a - [n/a	Not reported	ICSR
ELEC- 10012258737 20/04/2022 Spontaneous Healthcare Roofssional Economic Area Resolved - 20/04/2022 Spontaneous Non Resolved - 20/04/2022 Spontaneous Resolved - 20/04/2022 Spon											pain (n/a - Unknown			
ELEC- 10012258737 20/04/2022 Spontaneous Healthcare Roof- 10012258737 20/04/2022 Spontaneous Healthcare Roof- 10012258859 20/04/2022 Spontaneous Not reported (Seconding Area) ELEC- 10012258859 20/04/2022 Spontaneous Not reported (Seconding Area) Not reported (Seconding Area) Not reported (Seconding Area) Not Resolved - J., Seconding Area (Index Not Recovered/Not Recove											(n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10012258737 20/04/2022 Spontaneous Healthcare Professional European														
EU-EC- 20/04/2022 Spontaneous Non Healthcare Professional Area			Spontaneous		European Economic				Male	No	Chest pain (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10012258859 Non European Not Professional Area Not Years Specified Male No Collutitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivit (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)					71100						abnormal (n/a - Not Recovered/Not	.,(-1)		
EU-EC- 10012258859 20/04/2022 Spontaneous Non Healthcare Professional Area Not available Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Conjunctivitis (n/a - Recovering/Resolving - Other Medical											schedule of product administration (n/a - Unknown -),			
EU-EC- 10012258859 20/04/2022 Spontaneous Healthcare Professional Pro											Not Recovered/Not Resolved - Other Medically Important			
Healthcare Professional Profess											(n/a - Not Recovered/Not			
Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			Spontaneous	Healthcare	Economic				Ma l e	No	Recovering/Resolving - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important											Recovering/Resolving - Other Medically Important			
Recovering/Resolving - Other Medically Important											Recovering/Resolving - Other Medically Important			
											Recovering/Resolving - Other Medically			
Herpes ophthalmic (n/a - Recovering/Resolving - Other Medically Important Condition),											(n/a - Recovering/Resolving - Other Medically Important			

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										Herpes virus infection (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Immune system disorder (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nasal herpes (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Ocular hyperaemia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Periorbital swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Skin disorder (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012259601	20/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	1,41)	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012259861	20/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Abdominal pain lower (136d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	20/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Abdominal pain lower (n/a - Unknown -) Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012259887	20/04/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Crina	Male	NO	Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012260097	20/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	C-reactive protein increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Red blood cell sedimentation rate increased (n/a - Recovering/Resolving -)			
EU-EC- 10012260253	20/04/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Application site pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR

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				Area						Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10012260272	20/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10012260358	20/04/2022	Spontaneous		Economic	Not available	3-11 Years	Adult	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Rash (n/a - Not Recovered/Not			
EU-EC-	20/04/2022	Spontaneous	Healthcare		Not	3-11	Child	Female	No	Resolved -) Facial paralysis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10012260370 EU-EC-	20/04/2022	Spontaneous	Professional	Area	available	Years 3-11	Not	Female	No	Unknown -)	(S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	TCCI
10012261117	20/04/2022	Spontaneous		Non European Economic Area	Not available	Years	Specified	remale	INO	Arrhythmia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Chest pain (n/a - Recovering/Resolving -),			
										Cough (n/a - Recovering/Resolving -),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012240754	19/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012241567	19/04/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
EU-EC- 10012241998	19/04/2022	Spontaneous	Healthcare	Area European Economic Area	Not available	3-11 Years	Child	Male	No	Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation)	- 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10012242327	19/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

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										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012242517	19/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012242524	19/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012244523	19/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012244655	19/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012245454	19/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										COVID-19 (n/a - Unknown - Other Medically Important Condition),			
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Swelling face (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012247148	19/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Crying (n/a - Unknown -), Lymphadenopathy (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Lymphadenopathy (n/a - Unknown -)			
EU-EC- 10012248174	19/04/2022	Spontaneous	Non Healthcare Professional				Not Specified		No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Resolved -), Headache (n/a - Not Recovered/Not			
										Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10012248264	19/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving -), Nightmare (n/a -			
										Recovering/Resolving -), Pyrexia (n/a -			
EU-EC-	19/04/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Recovering/Resolving -) Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012250111			Professional	Economic Area	available	Years				(4d - Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012232771	18/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Illness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10012235152	18/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epstein-Barr virus infection (n/a - Unknown - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Life Threatening)			
EU-EC- 10012235289	18/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012235563	18/04/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012235767	18/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012235783	18/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	-) Asthenia (n/a - Recovered/Resolved -), Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
										Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a -			
EU-EC- 10012236614	18/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved -) Hallucination (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
										Insomnia (n/a - Recovered/Resolved			
EU-EC- 10012237632	18/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
										Resolved -), Pain (n/a - Not Recovered/Not Resolved -),			
										Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)			
EU-EC- 10012237950	18/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blood alkaline phosphatase decreased (11d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Blood lactate dehydrogenase increased (11d - Recovered/Resolved -),			
										Histiocytic necrotising lymphadenitis (363h			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Lymphadenopathy (11d - Recovered/Resolved -),			
										Neutrophil count decreased (11d - Recovered/Resolved -),			

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										Platelet count decreased (11d - Recovered/Resolved -),			
										Pyrexia (363h - Recovered/Resolved -),			
										White blood cell count decreased (11d - Recovered/Resolved			
EU-EC- 10012238543	18/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICS
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012238713	18/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Unknown -), Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICS
										(n/a - Unknown -), Vaccination site paraesthesia (n/a - Unknown -)			
EU-EC- 10012227395	17/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Malaise (2d - Recovered/Resolved -)			
EU-EC- 10012225094	16/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	, ,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10012217487	15/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Swelling (n/a - Unknown -)			
EU-EC- 10012218240	15/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dermatitis (n/a - Unknown -), Viral skin infection	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012218751	15/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	(n/a - Unknown -) Abdominal pain upper (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -), Pulmonary pain (n/a			
										- Not Recovered/Not Resolved -)			
EU-EC- 10012219933	15/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Drug ineffective (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10012222635	15/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Important Condition) Incorrect dose administered (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	COMIRNATY [TOZINAMERAN] (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSF
										Product dispensing error (1d - Recovered/Resolved -)			
EU-EC- 10012205752	14/04/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
			Professional							Pyrexia (n/a - Unknown -),	Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-	14/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Vomiting (n/a - Unknown -) Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10012205844	17/U4/2U22	Spontaneous		Economic	available	Years	Specified	тептаве	INU	(n/a - Not Recovered/Not Resolved -),	(S - Prophylaxis - Not applicable - [n/a - 1{DF} - Intramuscular])	mor reported	<u>1CSI</u>
										Pyrexia (n/a - Not Recovered/Not Resolved -),			

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										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012206620	14/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Heavy menstrual bleeding (n/a - Unknown -),			
										Inflammation (n/a - Unknown -),			
										Product administered to patient of inappropriate age (n/a - Unknown -),			
										Transfusion (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012206857	14/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	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	ICSI
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012206896	14/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Carditis (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	ICSF
										Chest pain (n/a - Not Recovered/Not Resolved -),			
										Lethargy (n/a - Not Recovered/Not Resolved -), Palpitations (n/a -			
										Not Recovered/Not Resolved -)			
EU-EC- 10012207049	14/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012207218	14/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Nasopharyngitis (n/a - Recovered/Resolved			
										- Caused/Prolonged Hospitalisation), Pyrexia (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012207478	14/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012207739	14/04/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Bell's palsy (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSF
EU-EC- 10012207778	14/04/2022	Spontaneous	Healthcare Professional	Area Non European	Not available	3-11 Years	Not Specified	Male	No	Condition) Abdominal pain (n/a	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSI
				Economic Area						Recovering/Resolving - Caused/Prolonged Hospitalisation),	Not applicable - [1d - n/a - Intramuscular])		
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-		Spontaneous		Non	Not	3-11	Not	Female	No	Loss of	COMIRNATY [TOZINAMERAN]	Not reported	ICSF

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				Economic Area						Recovered/Resolved - Other Medically Important Condition),	Not applicable - [1d - n/a - Intramuscular])		
										Vomiting (45min - Recovered/Resolved -)			
EU-EC- 10012208277	14/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012208572	14/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012208846	14/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012209007	14/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Muscular weakness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012209279	14/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved -),			
										Chills (n/a - Not Recovered/Not Resolved -),			
										Erythema (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain			
										(n/a - Not Recovered/Not Resolved -),			
EU-EC-	14/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -) Arthralgia (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012209743	11/01/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Cilia	lac		Recovered/Not Resolved -), Disturbance in	(S - n/a - n/a - [n/a - n/a - n/a])	Not reported	10010
EU-EC-	14/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	attention (n/a - Not Recovered/Not Resolved -) Apathy (42d - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012209916	1 1/0 1/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Cinia	T Idio		Recovered/Not Resolved -), Gastrointestinal pain	(S - Immunisation - n/a - [n/a - n/a - n/a])	The reported	1031
										(42d - Not Recovered/Not Resolved -),			
										Limb discomfort (42d - Not Recovered/Not Resolved -),			
										Nausea (42d - Not Recovered/Not Resolved -)			
EU-EC- 10012209970	14/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (1d - Recovering/Resolving			
EU-EC- 10012210210	14/04/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Ma l e	No	Abdominal pain (n/a	COMIRNATY CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR
				Area						Recovered/Resolved - Caused/Prolonged Hospitalisation),	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -		
										Arrhythmia supraventricular (n/a -	Intramuscular])		
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine			
										phosphokinase MB increased (n/a - Recovered/Resolved - Caused/Prolonged			

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										Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012210239	14/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Gastrointestinal sounds abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain (2d - Unknown - Caused/Prolonged Hospitalisation),			
										Rhinorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tenderness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (1d - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012210265	14/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gaze palsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012211302		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012213861	14/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012213907	14/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Varicella (n/a - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a2mt - n/a])	Not reported	ICSR
EU-EC- 10012216193	14/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012216278	14/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Crohn's disease (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Loss of personal independence in daily activities (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -), Weight decreased			
EU EC	12/04/222	Constitution	Haalet -	F	Niet	2.11	NI-*	Farris	NI:	(n/a - Unknown -)	COMIDNATY STORY	Nat name at 1	TOCO
EU-EC- 10012194451	13/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved -), Pyrexia (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a1mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10012195175		Spontaneous	Non Healthcare	Non European	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	[BECLOMETASONE DIPROPIONATE] (C - n/a -	ICSR

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			Professional	Economic Area						Fatigue (n/a - Unknown -),	Not applicable - [1d - n/a - n/a])	n/a - [n/a - n/a - n/a]), [CHLORPHENAMINE	
										Insomnia (n/a - Unknown -),		MALEATE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]),	
										Pain (n/a - Unknown -),		[MONTELUKAST, MONTELUKAST SODIUM] (C -	
										Peripheral swelling (n/a - Not		Hypersensitivity - n/a - [n/a - n/a - n/a])	
										Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown -),			
										Vaccination site swelling (n/a - Unknown -)			
EU-EC- 10012195521	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012195610	13/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012195646	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest X-ray abnormal (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Chest pain (n/a - Not Recovered/Not Resolved -),			
										Diabetic ketoacidosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Lethargy (n/a - Not Recovered/Not Resolved -),			
										Polydipsia (n/a - Not Recovered/Not Resolved -),			
										Polyuria (n/a - Not Recovered/Not Resolved -),			
										Tachycardia (n/a - Not Recovered/Not Resolved -),			
										Thirst (n/a - Not Recovered/Not Resolved -),			
										Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012195667	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Cutaneous vasculitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Decreased appetite (n/a - Not Recovered/Not Resolved -),			
										Epistaxis (n/a - Not			

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										Recovered/Not Resolved -), Haematuria (n/a - Not Recovered/Not			
										Resolved -), Inflammation (n/a - Not Recovered/Not Resolved -),			
										Neutrophilia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Splenomegaly (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012196113	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (10s - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012196431	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Pallor (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
FILEC	12/04/2022	Carabanana	Llaskk saus	Nee	Nak	2.11	Nat	Famala	Ne	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIDNADY FTO ZINAMEDANI	Networked	ICCD
EU-EC- 10012196543		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (0d - Recovered/Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012196739	13/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (3d - Recovered/Resolved -), Gait inability (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	<u>ICSR</u>
EU-EC- 10012196903	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	-) Acute lymphocytic leukaemia (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- 10012197121	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Limb injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012197122	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lethargy (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012197162	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Painful respiration (n/a - Recovering/Resolving -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012197289	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blood glucose decreased (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Dehydration (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012197319	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (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- 10012197709	13/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	[LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Diarrhoea (n/a - Recovering/Resolving -), Malaise (n/a -			
										Recovering/Resolving -), Vomiting (n/a -			
EU-EC- 10012197940	13/04/2022	Spontaneous		Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Recovering/Resolving -) Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Dyspnoea (n/a - Not Recovered/Not Resolved -),	n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lethargy (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012198017		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (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- 10012198912	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Abdominal rebound tenderness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012199432	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis perforated (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012200182	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012200604	13/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										COVID-19 (n/a - Fatal - Results in			

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										Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Cardiomyopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Drug ineffective (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Influenza like illness (n/a - Fatal - Results in Death),			
										Kidney transplant rejection (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Multisystem inflammatory syndrome (n/a - Fatal - Results in Death)			
EU-EC- 10012200851	13/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012201650	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Clonic convulsion (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lethargy (n/a - Recovering/Resolving -),			
										Muscular weakness (n/a - Recovering/Resolving -),			
										Mydriasis (n/a - Recovering/Resolving -),			
										Postictal state (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10012201686	13/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza like illness (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pain in extremity (2d - Recovered/Resolved -)			
EU-EC- 10012201950	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012202330	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Complicated appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Peritonitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10012202442	13/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012203064	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Drug ineffective (n/a -			

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012203641	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Limb discomfort (n/a - Not Recovered/Not Resolved -),			
										Muscle twitching (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012204447	13/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICS
EU-EC- 10012204701	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Complicated appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Intra-abdominal fluid collection (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012204775	13/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis perforated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10012205267	13/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICS
										Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012182123	12/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICS
										Oropharyngeal pain (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10012182128	12/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ecchymosis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	AERIUS [DESLORATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL	ICS
												HEMIFUMARATE] (C - n/a - n/a - n/a - n/a - n/a - n/a), [MONTELUKAST, MONTELUKAST SODIUM] (C -	
EU-EC- 10012182536		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	n/a - n/a - [n/a - n/a - n/a]) Not reported	ICS
EU-EC- 10012182972	12/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
			l								t and the second		

				Economic Area							Not applicable - [1d - n/a - n/a])		
EU-EC- 0012183795	12/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Condition) Autoimmune hepatitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Jaundice (n/a - Unknown -), Nausea (0d - Recovered/Resolved			
										-), Vomiting (0d - Recovered/Resolved -)			
U-EC- 0012184043	12/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No		COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	10
U-EC- 0012184249	12/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>IC</u>
U-EC- 0012184477	12/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovered/Resolved -), Nasal congestion (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	10
										Pyrexia (n/a - Recovered/Resolved -)			
U-EC- 0012185317	12/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Serum sickness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	Ī
U-EC- 0012186069	12/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	1
										Arthralgia (n/a - Not Recovered/Not Resolved -),			
										Diarrhoea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not			
U-EC-	12/04/2022	Spontaneous	Non	European	Not	3-11	Not	Male	No	Recovered/Not Resolved -) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN]	[ASCORBIC ACID] (C - n/a -	I
0012189365	12/04/2022	Spontaneous		Economic	available	Years	Specified	Male	NO	- Recovering/Resolving -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Erythema (n/a - Recovering/Resolving -), Fatique (n/a -			
										Recovering/Resolving -), Pyrexia (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving -)			
U-EC- 0012191727	12/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported]
										Chills (n/a - Recovering/Resolving -),			
										Erythema (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Nasal congestion (n/a - Recovering/Resolving -),			
										Oropharyngeal pain			

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										Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving			
										-), Rhinorrhoea (n/a - Recovering/Resolving -),			
										Throat irritation (n/a			
										Recovering/Resolving -),			
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012192085	12/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - n/a])	Not reported	<u>ICSR</u>
										Dizziness (6d - Recovered/Resolved -),			
										Headache (1d - Recovered/Resolved -),			
										Myalgia (6d - Recovered/Resolved -)			
EU-EC- 10012192923		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012192938	12/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Urticaria (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012169904	11/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dysphagia (10d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
										Paralysis (10d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (10d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012170302	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Clonic convulsion (10d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Epilepsy (10d - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (10d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012170350	11/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not			

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										Resolved - Other Medically Important Condition),			
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Product use issue (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012172028	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10012172034	11/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Electrocardiogram abnormal (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Pericarditis (n/a - Recovering/Resolving Other Medically Important Condition)			
EU-EC- 10012172042	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Muscle spasms (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Paraesthesia (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012172051	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (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
										Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012172057	11/04/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012172590		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012172602		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012172662	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Basedow's disease (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Hyperthyroidism (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012172750	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Hypoaesthesia (n/a - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Pain in extremity (n/a - Recovering/Resolving -),			
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012172772	11/04/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Dizziness (30min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
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				Economic Area						Syncope (30min - Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - n/a])		
EU-EC- 10012172789	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ocular hyperaemia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012174555	11/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (2d - Recovered/Resolved -), COVID-19 (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSI</u>
										Unknown -), Drug ineffective (n/a - Unknown -),			
FILE C	11/04/2022				Note	2.44	Child	N-L	N	Puncture site pain (3d - Recovered/Resolved -)	COMPNAT//TOTALAMEDAN		Tool
EU-EC- 10012175445	11/04/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eyelid oedema (n/a - Unknown -), Eyelid pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10012175591		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified		No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10012175608	11/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Recovered/Not Resolved -), Pallor (n/a - Not Recovered/Not			
										Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other			
=11.50	11/01/0000					2.44				Medically Important Condition)			
EU-EC- 10012175614	11/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved -), Electrocardiogram			
										abnormal (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -), Inappropriate			
										schedule of product administration (n/a - Unknown -), Myocarditis (n/a -			
										Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved -),			
										Troponin increased (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012175619	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-	11/04/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Male	No	 	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10012175642			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Respiratory symptom (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012175644	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Feeling abnormal (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012175654	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Gastroenteritis (n/a - Not Recovered/Not Resolved -),			
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012175662	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012175673	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10012175686	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved			
EU-EC- 10012175687	11/04/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012175689	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	n/a])		
										Vomiting (n/a -			
											•	•	

7.11.2022	 									Recovered/Resolved			
EU-EC- 10012175693	11/04/2022	Spontaneous		Economic	Not available	3-11 Years	Not Specified	Female	No	-) COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSF
				Area						Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	n/a])		
EU-EC- 10012175705	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea exertional (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Flushing (n/a - Not Recovered/Not Resolved -),			
										Heart rate increased (n/a - Not Recovered/Not Resolved -),			
										Influenza like illness (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Respiratory distress (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Wheezing (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012175843		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012175847	11/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Myoclonus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tic (n/a - Unknown -			
EU-EC- 10012175856	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Myocarditis (1443min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC-	11/04/2022	Spontaneous		Non	Not	3-11	Not	Male	No	Important Condition) Dyspnoea (2310min	 	Not reported	ICSR
10012175892		·	Professional	European Economic Area	available	Years	Specified			- Recovered/Resolved - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012176790		Spontaneous	Professional	Economic Area	Not available	3-11 Years	Not Specified	Male	No	Panniculitis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012176798	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (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- 10012176801	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not			
										Recovered/Not Resolved -), Paraesthesia (n/a -			
										Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not			
										Resolved - Other Medically Important Condition),			

										Throat tightness (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012176810	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	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	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012176811	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012176855	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012176860	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012176868	11/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Corneal laceration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Iridocele (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Uveal prolapse (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012176952	11/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Hemiparesis (24h - Recovered/Resolved -), Hypoaesthesia (24h -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved -), Paraesthesia (24h - Recovered/Resolved			
EU-EC-	11/04/2022	Spontaneous		European	Not	3-11	Child	Female	No	-) Gastrointestinal	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012177554			Healthcare Professional	Economic Area	available	Years				disorder (1d - Recovered/Resolved -), Influenza like illness	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
										(3d - Recovered/Resolved			
EU-EC- 10012177622	11/04/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	[CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved -),	Intramuscular])	indication - n/a - [n/a - n/a - n/a])	
										Diarrhoea (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012178868	11/04/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hyperacusis (n/a - Unknown -),			
										Hyperhidrosis (2d - Recovered/Resolved -),			
										Loss of consciousness (5d - Recovered/Resolved			

										- Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pallor (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown -),			
										Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012178904	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012179095	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012179779	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012180400	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blood pressure decreased (40min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Bradycardia (40min - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved -),			
										Malaise (n/a - Recovered/Resolved -), Presyncope (n/a -			
EU-EC-	11/04/2022	Spontaneous	Non	Non	Not	3-11	Not	Male	No	Recovered/Resolved -) Blood triglycerides	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012180666	11/01/2022	Sportaneous	Healthcare	European Economic Area	available	Years	Specified	ridic		abnormal (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSIC
										COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	,		
										Drug ineffective (n/a			
										Recovering/Resolving - Other Medically Important Condition),			
										Limb discomfort (1d - Recovered/Resolved			
										Product administered to patient of inappropriate age			
EU-EC- 10012180686	11/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	(n/a - Unknown -) Gait disturbance (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012180714	11/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a -	Not reported	ICSR
EU-EC- 10012180747	11/04/2022	Spontaneous		Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Hyperhidrosis (n/a - Recovered/Resolved -),	n/a])		
										Syncope (n/a -			

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012180900	11/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash pruritic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012181331	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012181711	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthritis (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Blood alkaline phosphatase decreased (n/a - Unknown -),			
										Eye swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Gait disturbance (n/a			
										Recovered/Resolved - Other Medically Important Condition),			
										Grip strength decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Inflammation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Joint swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral swelling			
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Polyarthritis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown -),			
										Rash (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012181717	11/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Nasopharyngitis (n/a			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	10/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Lip oedema (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10012169521	10/04/2022	Sportaneous	Healthcare	Economic	available	Years	Specified		INU	Recovering/Resolving -), Malaise (n/a -	(S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	not reported	1031
										Recovering/Resolving -), Oral herpes (n/a -			
EU-EC-	00/04/2022	Coorter	Hoolth	Europe	Not	2 11	Child	Eom: -!-	Na	Recovering/Resolving -)	COMIRNATY [TOZINAMERAN]	Not reported	Too
10012167797	U5/U4/2U22	Spontaneous	Professional	European Economic	available	3-11 Years	Ciniu	Female	No	Axillary pain (n/a - Recovering/Resolving	(S - COVID-19 immunisation -	Not reported	ICSE

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				Area						-), Headache (n/a - Recovering/Resolving -),	Not applicable - [n/a - 1{DF} - Intramuscular])		
										Lymphadenopathy (n/a - Recovering/Resolving			
EU-EC- 10012154958	08/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	-) Arthralgia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
										Asthenia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Erythema (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012156653	08/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSR
										Feeling cold (n/a - Unknown -),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Neck pain (n/a - Unknown -),			
511.50	20 /0 / /0 000									Pain in extremity (n/a - Unknown -)			
EU-EC- 10012159779	08/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pallor (n/a - Unknown -)			
EU-EC- 10012159914	08/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Face injury (n/a - Unknown -), Fall (n/a - Unknown -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
										Syncope (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012160175	08/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Basedow's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperthyroidism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN] [TOZINAMERAN] (5 - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN	<u>ICSR</u>
												(A/HONG KONG/4801/2014, X-263B), B/RISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - n/a - n/a - [1d - n/a - n/a]),	
												[AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - n/a - n/a - 15mg - n/a]), [DIPHTHERIA AND TETANUS	
												TOXOIDS AND PERTUSSIS] (C - n/a - n/a - [1d - n/a - n/a]), [MENINGOCOCCAL VACCINE]	
T	I	I	I	I	I	1	I	I	I	I	I	I	

												(C - n/a - n/a - [1d - n/a - n/a])	
EU-EC- 1.0012160748	08/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Other Medically Important Condition)			
EU-EC- 10012160952	08/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Joint effusion (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012161739	08/04/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Immunisation reaction (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Incorrect dose administered (1d - Recovered/Resolved -)			
EU-EC- 10012162147	08/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Abdominal pain upper (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition),	TOZINAMERAN] [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Abdominal pain upper (n/a - Unknown -),			
										Acute kidney injury (n/a - Unknown - Other Medically Important Condition),			
										Constipation (n/a - Unknown -),			
										Decreased appetite (n/a - Recovered/Resolved With Sequelae - Disabling),			
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Flushing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Gastrooesophageal reflux disease (n/a - Recovered/Resolved With Sequelae - Disabling),			
										Loss of personal independence in daily activities (n/a - Unknown -),			
										Nausea (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
711.50	00/04/555	Court	Neg	New	Net		No.	M-1		Tremor (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOTTIANTE		
EU-EC- 10012164393	u8/U4/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown -), Acute kidney injury (n/a - Unknown - Other Medically	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC

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										Condition), Acute respiratory failure (6d - Recovered/Resolved - Other Medically Important Condition),			
										Asthenia (n/a - Unknown -),			
										Fatigue (n/a - Unknown -),			
										Gastrooesophageal reflux disease (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Hyperhidrosis (6d - Recovered/Resolved -),			
										Hypotension (6d - Recovered/Resolved -),			
										Inflammation (n/a - Unknown -),			
										Nausea (n/a - Recovered/Resolved With Sequelae - Disabling),			
										Oxygen saturation abnormal (n/a - Recovered/Resolved With Sequelae -),			
										Pallor (n/a - Recovered/Resolved With Sequelae -),			
										Palpitations (n/a - Recovered/Resolved With Sequelae -),			
										Tremor (n/a - Recovered/Resolved With Sequelae -)			
EU-EC- 10012165123	08/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Rash maculo-papular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012165720	08/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10012165740	08/04/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012138983	07/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012139035	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012139320	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bone pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
										Cough (n/a - Unknown -),	Intramuscular])		
										Fatigue (n/a - Unknown -),			
EU-EC-	07/04/2022	Spontaneous	Non	European	Not	3-11	Not	Male	No	Pyrexia (n/a - Unknown -) Pityriasis rosea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012139355			Healthcare Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012141498	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Joint swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012141587	07/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Loss of consciousness (0d - Recovered/Resolved			

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										- Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012141770	07/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash vesicular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012141888	07/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (6d - Recovered/Resolved -), Lymphadenopathy (6d - Recovered/Resolved -),	COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC-	07/04/2022	Spontaneous	Llosliboaro	- Furances	Not	3-11	Not	Female	No	Poor quality sleep (6d - Recovered/Resolved -), Pyrexia (6d - Recovered/Resolved -) Headache (n/a - Not	COMIRNATY 10	Not reported	ICCD
10012141927			Professional	European Economic Area	available	Years	Specified	гентане		Recovered/Not Resolved - Disabling), Photophobia (n/a - Not Recovered/Not Resolved - Disabling)	MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a2mL - n/a])	Not reported	ICSR
EU-EC- 10012142311	07/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Hypersensitivity (n/a - Unknown -), Periorbital swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012142855	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	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} - n/a])	Not reported	ICSR
EU-EC- 10012145926	07/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Cough (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
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -),			
511.50	07/04/2022			-	N	2.44	CI II	- · · ·		Throat irritation (n/a - Not Recovered/Not Resolved -)	COMPANY (TO THAN ED AN)		TOOD
EU-EC- 10012147836		Spontaneous	Healthcare Professional	Economic Area	Not available	3-11 Years	Child	Female	No	Herpes zoster (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 10ug - Intramuscular])	Not reported	ICSR
EU-EC- 10012149315	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (2d - Recovered/Resolved -), Influenza (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Urticaria (n/a - Not Recovered/Not Resolved -), Urticaria (n/a -			
EU-EC- 10012150997	07/04/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Male	No	Recovered/Resolved -) Application site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional			100.0				Recovered/Resolved -), Headache (n/a - Recovered/Resolved	n/a - [n/a - 1{DF} - n/a])		
										Pyrexia (n/a - Recovered/Resolved			
EU-EC- 10012152198	07/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Feeling hot (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012152608	07/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oropharyngeal pain (n/a - Unknown -) Cough (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Pyrexia (n/a - Unknown -), Vaccination site pain	Unknown])		
EU-EC- 10012152638	07/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	(n/a - Unknown -) Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Vaccination site pain (n/a - Unknown -)	Unknown])		

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EU-EC- 10012127743	06/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hallucination, auditory (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Nervousness (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012127808	06/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012128124	06/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012128489	06/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypersensitivity (n/a - Unknown - Caused/Prolonged Hospitalisation), Multisystem	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a2mL -	Not reported	ICSR
										inflammatory syndrome in children (n/a - Unknown - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10012129022	06/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Administration site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lymph node pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012129747	06/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -), Physical deconditioning (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown -), Pyrexia (n/a - Unknown - Other Medically Important			
EU-EC- 10012129824	06/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012129873	06/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
										Arthritis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Gait disturbance (n/a - Recovering/Resolving			
										-), Swelling (n/a -			
EU-EC- 10012130586	06/04/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Unknown -) Arthralgia (n/a - Not Recovered/Not	COMIRNATY 10 MICROGRAMS/DOSE	Not reported	ICSR
			Professional			30.0				Resolved - Disabling), Emotional distress	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not		
										(n/a - Not Recovered/Not Resolved -	applicable - [n/a - n/a - n/a])		

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										Disabling), Injected limb mobility decreased (n/a - Not Recovered/Not Resolved - Disabling),			
										Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling),			
FILEG	06/04/2022				Number	2.44	CLIL		V	Vaccination site joint pain (n/a - Not Recovered/Not Resolved - Disabling)			TOOD
EU-EC- 10012131247	06/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	Yes	Angina pectoris (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin I increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012131873	06/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bronchiolitis (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular]),	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE] (C - Nasal	ICSR
										Dark circles under eyes (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN	congestion - n/a - [n/a - n/a - Nasal])	
										Lacrimation increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[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-2638),		
										Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - Not applicable - [1d - n/a -		
EU-EC- 10012132728	06/04/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10012133683	06/04/2022	Spontaneous	Non Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Drug ineffective (n/a - Unknown - Other Medically Important Condition),	n/a - [n/a - 10ug - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
				_						Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012133860	06/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Child	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Not Resolved -)			
EU-EC- 10012134417	06/04/2022	Spontaneous			Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Illness (n/a - Recovered/Resolved			
										-), Inappropriate schedule of product administration (n/a -			
										Unknown -), Pallor (n/a - Recovered/Resolved -),			
										Paraesthesia (n/a - Recovered/Resolved			

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										-), Somnolence (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012134664	06/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary pain (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Pain in extremity (5d - Recovered/Resolved -)			
EU-EC- 10012135155	06/04/2022	Spontaneous	Healthcare		Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012135396	06/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dehydration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012137365		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d2mL - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC- 10012137441	06/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012137525	06/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Condition aggravated (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
										Dermatitis atopic (n/a - Recovering/Resolving -)			
EU-EC- 10012137561	06/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Alopecia areata (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012137644	06/04/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Female	No	Diarrhoea (0d - Recovered/Resolved -), Headache (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Injection site pain (1d -			
EU-EC-	06/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012137645	, ,	-			available	Years				Recovering/Resolving -), Cold sweat (0d -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovering/Resolving -), Dizziness (0d -			
										Recovering/Resolving -), Syncope (0d - Recovering/Resolving - Other Medically			
										Important Condition), Vaccination site pain (0d -			
EU-EC- 10012115116	05/04/2022	Spontaneous	Healthcare Professional		Not	3-11 Years	Not Specified	Female	No	Recovering/Resolving -) Vaccination site pain	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
EU-EC-	05/04/2022	Spontaneous		Area European	available Not	Years 3-11	Specified Not	Female	No	(2d - Recovered/Resolved -) Vaccination site pain	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012115119			Professional	Economic Area	available	Years	Specified			(0d - Recovered/Resolved -)	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		
EU-EC- 10012115121	U5/U 4 /2022	Spontaneous			Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (4d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Diarrhoea (4d - Recovered/Resolved - Other Medically Important			

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										Condition), Rectal haemorrhage (4d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (4d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012115291	05/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Warm autoimmune haemolytic anaemia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012115632	05/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (35min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (35min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012116405	05/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012116444	05/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dengue virus test positive (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving -),			
										Rash (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10012117755	05/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fall (n/a - Unknown -), Pallor (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012117903	05/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Generalised tonic- clonic seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Pyrexia (n/a - Unknown -),			
EU-EC-	05/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Vomiting (n/a - Unknown -) Fall (0d -	COMIRNATY [TOZINAMERAN]	[SALBUTAMOL, SALBUTAMOL	ICCD
10012118435	05/04/2022	Spontaneous	Healthcare	Economic Area	available	Years	Specified	remale	NO	Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	SALBOTAMOL, SALBOTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Fear of injection (n/a - Unknown -),			
										Stress (n/a - Unknown -),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012119511	05/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012120492	05/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012120508	05/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Cough (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovered/Resolved			

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										- Caused/Prolonged Hospitalisation),			
										Heart rate increased (n/a - Unknown -),			
										Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Respiratory rate increased (n/a -			
EU-EC- 1001212177		Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Unknown -) Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chills (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Oedema (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
EU EC	05/04/2022	Carabanana	I I a slikk same	Nan	NI-L	2.11	Nat	Farrala	NI-	Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) Blood pressure	COMIDNADA FTO ZINAMEDANI	Not received	TOCO
EU-EC- 1001212180		Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	increased (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
				71100						Dizziness (n/a - Recovering/Resolving -),	Indunascular ()		
										Headache (n/a - Recovering/Resolving -),			
										Hypoaesthesia (n/a - Unknown -), Loss of			
										consciousness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 1001212232		Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001212253		Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Brain oedema (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
										Dyskinesia (n/a - Unknown - Other Medically Important Condition),			
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Myoclonus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Neurological			

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										symptom (n/a - Unknown - Other Medically Important Condition),			
										Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vasodilatation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vein discolouration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012123116	05/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Cyanosis (n/a - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-	Not reported	ICSR
										Recovering/Resolving -), Impaired quality of life (n/a -	19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Loss of personal independence in			
										daily activities (n/a - Recovered/Resolved -), Nail discolouration			
										(n/a - Recovered/Resolved -),			
Ell EQ	05/04/2022		I I a lith a sur	F	Note	2.11	Child	F	N	Oxygen saturation abnormal (n/a - Recovered/Resolved -)	COMPNATA TOTAL MED AND	N. L. C.	TOCO
EU-EC- 10012123493	05/04/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Chest discomfort (n/a - Unknown -), Syncope (2s - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012124611	05/04/2022	Spontaneous	Healthcare		Not available	3-11 Years	Not Specified	Female	No	Tinnitus (n/a - Unknown -) Genital haemorrhage (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10012125854	05/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Important Condition) Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012125864	05/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Lip oedema (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012125867	05/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012095943	04/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (13h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (13h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012095992	04/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cough (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012097108	04/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Death) COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012097603	04/04/2022	Spontaneous		Economic	Not available		Not Specified	Female	No	Abdominal pain upper (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved - Recovered/Resolved	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012098517	04/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	-) Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus arrhythmia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012099088	04/04/2022	Spontaneous	Healthcare		Not available		Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])	Not reported	ICSR
EU-EC- 10012101058	04/04/2022	Spontaneous		Economic	Not available	3-11 Years	Not Specified	Male	No	Cold sweat (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012101343	04/04/2022	Spontaneous		Economic	Not available		Not Specified	Male	No	Fall (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012102733	04/04/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Erythema (15min - Recovered/Resolved -), Hypoaesthesia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Raraesthesia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash erythematous (n/a - Recovered/Resolved -), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CEFUROXIME, CEFUROXIME AXETIL] (C - Nasopharyngitis - n/a - [n/a - n/a - n/a])	ICSR

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									Condition), Tremor (n/a - Unknown -)			
04/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
									Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
									Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)			
04/04/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
									- Unknown - Other Medically Important Condition)			
04/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
04/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
									Headache (n/a - Unknown -),			
									(n/a - Unknown -), Vaccination failure			
									Other Medically Important Condition)			
04/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years			No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
04/04/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - n/a])	Not reported	ICSF
04/04/2022					2.44	N. I			Product administered to patient of inappropriate age (n/a - Unknown -)	COMPANY (FOUNDAMED AND		1001
04/04/2022	Spontaneous	Professional	Economic Area	available	3-11 Years			No	increased (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSF</u>
									Recovered/Resolved -),			
									Dysphagia (n/a - Recovered/Resolved -),			
									Livedo reticularis (n/a - Recovered/Resolved -),			
									Pallor (n/a - Recovered/Resolved -),			
									Somatic symptom disorder (n/a - Recovered/Resolved -),			
									Urticaria (n/a - Recovered/Resolved -)			
04/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Myelodysplastic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
									Pancytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
04/04/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years			No	Chest pain (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSF
	04/04/2022 04/04/2022 04/04/2022 04/04/2022	D4/04/2022 Spontaneous	D4/04/2022 Spontaneous Non Healthcare Professional D4/04/2022 Spontaneous Non Healthcare Professional D4/04/2022 Spontaneous Non Healthcare Professional D4/04/2022 Spontaneous Healthcare	D4/04/2022 Spontaneous Non Healthcare Professional Economic Area D4/04/2022 Spontaneous Healthcare Professional Economic Area D4/04/2022 Spontaneous Non Healthcare Professional Economic Area D4/04/2022 Spontaneous Non Healthcare Professional Economic Area D4/04/2022 Spontaneous Non Healthcare Professional Economic Area D4/04/2022 Spontaneous Healthcare Professional Economic Area	Da/04/2022 Spontaneous Non Healthcare Professional	D4/04/2022 Spontaneous Non Healthcare Professional Regularization Professional Profe	Non	Non Healthcare Professional P	Non	Pay Pay	2009/17/2022 Sporthamesea Parameter Parameter	Section of the continue of t

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EU-EC- 10012105802	04/04/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Pancreatitis acute (3d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [8d - 1{DF} - Intramuscular]),	Not reported	<u>ICSR</u>
										Hospitalisation)	ESOMEPRAZOLE [ESOMEPRAZOLE] (S - Product used for unknown indication - Dose not changed - [n/a - 20mg - Oral]),		
											[ACICLOVIR] (S - Prophylaxis - Dose not changed - [n/a - 800mg - Oral]),		
											[CICLOSPORIN] (S - Chronic graft versus host disease - Dose not changed - [n/a - 30mg - Oral]),		
											[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN BENZATHINE] (S - Prophylaxis - Dose not changed - [n/a - 750000[iU] - Oral]),		
											[RUXOLITINIB PHOSPHATE] (S - Product used for unknown indication - Dose not changed - [n/a - 5mg - Oral]),		
											[SULFAMETHOXAZOLE, TRIMETHOPRIM] (S - Prophylaxis - Dose not changed - [n/a - n/a - Oral]),		
											[URSODEOXYCHOLIC ACID] (S - Hepatobiliary disease - Dose not changed - [n/a - 300mg - Oral])		
EU-EC- 10012106647	04/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012106927	04/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012107072	04/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012107073	04/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Face injury (n/a - Unknown -), Fall (n/a - Unknown -	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Presyncope (n/a -			
EU-EC- 10012107105	04/04/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Unknown -) Asthenia (n/a - Unknown -),	COMIRNATY 10 MICROGRAMS/DOSE	Not reported	ICSR
			Professional	Area						Fall (n/a - Unknown -)	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012108132	04/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOBAZAM] (C - n/a - n/a -	ICSR
EU-EC- 10012108133	04/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[n/a - n/a - n/a]) Not reported	ICSR
				Area						Condition),	n/a])		

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										- Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown -),			
										Pain in extremity (n/a - Unknown -)			
EU-EC- 10012112249	04/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Administration site lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012112250	04/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012112774	04/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012113982	04/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10012114119	04/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Pruritus (n/a - Unknown -), Pyrexia (1d -			
										Recovered/Resolved -), Rash (n/a - Unknown			
										Urticaria (n/a -			
EU-EC- 10012080207	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Unknown -) Rash (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC- 10012080213	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Product administration error (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10012080935	01/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	- Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012080959	01/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012080961	01/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (8min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012081072	01/04/2022	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),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
										Fatigue (n/a - Unknown -),			
										Nasopharyngitis (n/a - Unknown -),			
										Rash erythematous (n/a - Recovered/Resolved -),			
										Skin exfoliation (n/a - Unknown -),			
										Vaccination site erythema (n/a - Unknown -)			
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0.11.2022 (EU-EC- 10012081264		Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified		No	Condition aggravated (n/a - Unknown - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Motion sickness (n/a - Unknown - Disabling), Nausea (1d - Recovered/Resolved	Intramuscular])		
										With Sequelae - Disabling), Vomiting (1d -			
										Recovered/Resolved With Sequelae - Disabling)			
EU-EC- 10012081966	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Amnesia (n/a - Recovered/Resolved -), Disorientation (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Tearfulness (n/a - Recovered/Resolved			
										-), Urinary incontinence (n/a - Recovered/Resolved			
EU-EC-	01/04/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	-) Decreased appetite	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012082374	91/01/2022	opolitaine e a		Economic	available	Years	G.IIIG			(n/a - Recovered/Resolved -),	(S - n/a - n/a - [n/a - n/a - n/a])		10011
										Headache (n/a - Recovered/Resolved -), Pyrexia (n/a -			
										Recovered/Resolved -), Vomiting (n/a -			
EU-EC-	01/04/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Recovered/Resolved -) Chills (1d -	COMIRNATY [TOZINAMERAN]	[MACROGOL 4000] (C - n/a -	ICSR
10012083619	01/01/2022	Sportericous		Economic	available	Years	Specified	Temale		Recovered/Resolved -), Malaise (1d -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - [n/a - n/a - n/a])	10010
										Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -)			
EU-EC- 10012084124	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Muscular weakness (n/a - Unknown -),			
										Somnolence (n/a - Unknown -)			
EU-EC- 10012087608	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (15d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012087728	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Female	No	Crying (n/a - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	ICSR
			FIOLESSIONAL	Alea						Emotional distress (n/a - Recovered/Resolved	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Joint contracture (n/a - Recovered/Resolved -),			
										Nervousness (n/a - Recovered/Resolved -),			
										Panic attack (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved			
EU-EC- 10012087769	01/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-) Capillary nail refill test abnormal (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (14min - Recovered/Resolved - Other Medically Important			
										Condition), Hypotension (n/a -			
										Unknown - Other			

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<u></u>							a			Medically Important Condition)	leasures :=:		_
EU-EC- 10012088641	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Gastrointestinal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Muscle spasms (n/a - Recovered/Resolved -)			
EU-EC- 10012088875	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fall (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10012089028	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10012089168	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Erythema (8min - Recovered/Resolved -), Pruritus (8min - 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	ICSI
EU-EC- 10012089169	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Disorientation (n/a - Unknown -), Dizziness (n/a - Recovered/Resolved -), Petit mal epilepsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012089191	01/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (20min - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012089207	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Mucosal disorder (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10012089315	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Pallor (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012089316	01/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Unknown - Other Medically Important Condition), Lymphadenitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mg - Intramuscular])	Not reported	ICSF
EU-EC- 10012089401	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSF
EU-EC- 10012089720	01/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF

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										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012089816	01/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Tic (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- 10012091114	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012091191	01/04/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012069677	31/03/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Contusion (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Pustule (n/a - Not Recovered/Not Resolved -),			
										Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012070824	31/03/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012071357	31/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dermatitis bullous (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a - More in ICSR])	Not reported	ICSR
										Ichthyosis acquired (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012072012	31/03/2022		Non Healthcare Professional	European Economic Area		3-11 Years	Child	Female	No	Erythema multiforme (50d - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (50d - Recovering/Resolving -)			
EU-EC- 10012072014	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Chi l d	Male	No	Cardiovascular disorder (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved -),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012072033	31/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Strabismus (100d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012072050	31/03/2022	Spontaneous	Non	European Economic	Not available	3-11 Years	Child	Male	No	Rash (20d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
EU-EC- 10012072727	31/03/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Local reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012072747	31/03/2022	Spontaneous		European Economic	Not available	3-11 Years	Child	Female	No	Fatigue (45d - Unknown -), Petechiae (45d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU EC	21/02/2022	Coortes	Non	Euross	Not	2 1 1	Child	Ears-1:	Ne	Rash (45d - Unknown -)	COMIDNATA FTOZINAAFDANI	Not roports d	Iccr
EU-EC- 10012072748			Healthcare Professional		Not available	3-11 Years	Child	Female	No	Tonsillar hypertrophy (37d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012072755	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Nail injury (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC-	31/03/2022	Spontaneous		European	Not	3-11	Child	Female	No	-) Fatigue (7d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10012072756	24 (22 (222			Economic Area	available	Years				Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10012072764	31/03/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a - More in ICSR])	Not reported	ICSF
										Panniculitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012072783	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (43d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Influenza like illness (43d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012072822	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Chi l d	Female	No	Headache (29d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (29d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10012073044	31/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012074690	31/03/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Gastroenteritis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	OLOPATADINE HYDROCHLORIDE [OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a -	ICSF
										Gastrointestinal hypomotility (n/a - Unknown -), Vomiting (n/a -		n/a - Oral])	
EU-EC- 10012075960	31/03/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Unknown -) Subglottic laryngitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10012077971	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Supraventricular tachycardia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation,	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	[FLUTICASONE PROPIONATE, SALMETEROL] (C - Asthma - Unknown - [n/a - 2{DF} - n/a]),	ICSR
										Other Medically Important Condition)		[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - Unknown - [n/a - n/a - n/a])	
EU-EC- 10012078400	31/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (n/a - Unknown -), Increased viscosity of upper respiratory secretion (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
										Somnolence (n/a - Unknown -)			
EU-EC- 10012078493		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012078798	31/03/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012078877	31/03/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Other Medically Important Condition),	(COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular])	Not reported	ICSR
										Cough (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Sensation of foreign body (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-	30/03/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Thrombocytopenia	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10012055384			Healthcare Professional	Economic Area	available	Years	Specified			(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012056819	30/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 - n/a - [n/a3ml Intramuscular])	Not reported	ICSR
										Vomiting (0d - Recovered/Resolved			
EU-EC- 10012056954	30/03/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Agitation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Crying (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hallucination (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012056977	30/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovering/Resolving -),			
										Off label use (n/a - Unknown -),			
										Somnolence (n/a - Recovering/Resolving -),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012057157	30/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash erythematous (4d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
										Rash pruritic (4d - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012057173	30/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - 2{DF} - n/a])	ICSR
										Product administered to patient of inappropriate age	1,74])		
EU-EC- 10012057218	30/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	(n/a - Unknown -) Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Skin lesion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012057675	30/03/2022	Spontaneous	Non Healthcare	Non European	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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			Professional	Economic Area						Recovering/Resolving - Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Neck pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 1001205790	30/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fall (0d - Recovered/Resolved -), Loss of	COMIRNATY 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - 1(DF) -	Not reported	<u>ICSR</u>
										consciousness (n/a - Recovered/Resolved -), Malaise (0d -	Intramuscular])		
EU-EC-	30/03/2022	Spontaneous	Non	European	Not	3-11	Adult	Female	No	Recovered/Resolved -) Disturbance in	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
1001205791		эропшисов	Healthcare	Economic Area	available	Years	Addit	Temale		attention (3d - Recovered/Resolved -),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSIX
										Influenza (35d - Recovered/Resolved -)			
EU-EC- 1001205878		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (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
										C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Feeling of body temperature change (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Laboratory test abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
	1	1	I	I						Myalgia (n/a - Not Recovered/Not			
										Resolved - Caused/Prolonged Hospitalisation),			
										Caused/Prolonged			
										Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged			

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										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012060416	30/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Feeling cold (3wk - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Gastrointestinal pain (3wk - Recovered/Resolved -),			
										Headache (3wk - Recovered/Resolved -)			
EU-EC- 10012060685	30/03/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012060704	30/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Diarrhoea haemorrhagic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012062317	30/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SODIUM VALPROATE] (C - Petit mal epilepsy - n/a - [n/a - 13.5mL - n/a - More in ICSR])	ICSR
										Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tonic convulsion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10012062879	30/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Ventricular extrasystoles (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012065962	30/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Depressed mood (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
										Hypothermia (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012041854	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (7d - Recovered/Resolved -), Haematoma (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										-), Myalgia (7d -			

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EU-EC- 10012041863	29/03/2022	Spontaneous		Economic	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Abdominal pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Area						Chest pain (3d - Recovered/Resolved -),	n/a - [n/a2mL - Intramuscular])		
										Headache (3d - Recovered/Resolved -)			
EU-EC- 10012041866	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012041881	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (7d - Recovered/Resolved -), Myalgia (7d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	ILARIS [CANAKINUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										-), Paraesthesia (7d - Recovered/Resolved -),			
										Pyrexia (7d - Recovered/Resolved -)			
EU-EC- 10012041885	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Decreased appetite (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Hyperpyrexia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10012041895	29/03/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Hyperpyrexia (7d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Urticaria (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012041899		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)		Not reported	ICSR
EU-EC- 10012041950	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL -	Not reported	ICSR
EU-EC- 10012041982	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (6d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Diarrhoea (6d - Recovered/Resolved -),			
										Pyrexia (6d - Recovered/Resolved -),			
										Vomiting (6d - Recovered/Resolved -)			
EU-EC- 10012041990	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Headache (7d - Recovered/Resolved -), Myalgia (7d -			
EU-EC-	29/03/2022	Spontaneous		European	Not	3-11	Not	Female	No	Recovered/Resolved -) Eye movement	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012042074			Professional	Economic Area	available	Years	Specified			disorder (2d - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		

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										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (2d - Recovered/Resolved - Other Medically Important Condition),			
	20/02/2002									Tremor (2d - Recovered/Resolved - Other Medically Important Condition)			1000
EU-EC- 10012042591	29/03/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
				Arcu						Feeling abnormal (n/a - Unknown -),	1,41)		
										Hemiparesis (n/a - Unknown - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Unknown -),			
EU EC	20/02/2022	Constant	1114	F	Nich	2.44	NI-t	FI-	N.	Paraesthesia (n/a - Unknown -)	COMMENTATIVE TOTAL AMERICAN	N. b	TOOD
EU-EC- 10012045051	29/03/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Overdose (n/a - Unknown -), Pain in extremity (24h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	Not reported	ICSR
EU-EC-	20/03/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Recovered/Resolved -) Malaise (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012046168	29/03/2022	Sportaneous	Professional		available	Years	Crind	remale		Recovered/Resolved - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSK
										Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012046474	29/03/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Fema l e	No	Application site swelling (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Lymphadenitis (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012046612	29/03/2022	Spontaneous		Economic	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving -),			
										Somnolence (n/a - Recovering/Resolving -)			
EU-EC- 10012046831	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bacterial infection (n/a - Recovered/Resolved	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	<u>ICSR</u>
										-), Hypersensitivity (n/a	DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not		
										- Recovered/Resolved -),	applicable - [n/a - n/a - n/a])		
										Rash erythematous (3d - Recovered/Resolved -),			
										Rash papular (3d - Recovered/Resolved -),			
										Vaccination site infection (n/a - Recovered/Resolved -),			
										Vaccination site rash (3d - Recovered/Resolved -)			
EU-EC- 10012047616	29/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injury (n/a - Unknown -), Off label use (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown -), Product use issue (n/a - Unknown -),			
										Respiratory arrest (n/a - Unknown -			
I	I	I	I	I	I	I	I		I	I	I	I	

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										Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012047716	29/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Inappropriate schedule of product administration (2d - Unknown -), Vaccination site pain (2d - Recovered/Resolved -), Wound complication (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, COLECALCIFEROL, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, THIAMINE, VITAMIN B6, PANTHENOL, RETINOL, ALPHA-TOCOPHEROL, RIBOFLAVIN PHOSPHATE] (C - Vitamin supplementation - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - Vitamin D - n/a - [n/a - n/a - Oral]), [FISH OIL] (C - Supplementation therapy - n/a - [n/a - n/a - Oral]), [LAMOTRIGINE] (C - Brain injury - n/a - [n/a - n/a -	ICSR
EU-EC- 10012047742	29/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (111h - Recovered/Resolved - Other Medically Important Condition), Haematochezia (5d - Recovered/Resolved - Other Medically Important Condition), Moaning (127h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Oral]) Not reported	ICSR
EU-EC- 10012048130	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (7h - Recovered/Resolved -) Headache (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012049691	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Resolved -) Injection site erythema (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Vaccination site oedema (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012049693	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Oropharyngeal pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} -	Not reported	ICSR
EU-EC- 10012050441	29/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified		No	-) Ear swelling (n/a - Unknown -), Swelling face (n/a - Recovered/Resolved -), Urticaria (n/a - Unknown - Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012050497	29/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012051066	29/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	Yes	Epididymitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012051140	29/03/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (3d - Recovered/Resolved -), Decreased appetite (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICSR

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										-), Pain (3d - Recovered/Resolved			
										Pyrexia (3d - Recovered/Resolved			
EU-EC- 10012052187	29/03/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Not Specified	Female	No	Headache (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Nausea (1d - Recovered/Resolved			
EU-EC- 10012052449	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Taste disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC- 10012052504	29/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012052554	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]),	[DOMPERIDONE] (C - Nausea - n/a - [n/a - n/a - n/a])	ICSR
											IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Migraine - Unknown - [n/a - n/a - Oral])		
EU-EC- 10012052581	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dehydration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012052654	29/03/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	3-11 Years	Child	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012052660	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hypotension (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10012052725	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site rash (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012053266	29/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Malaise (n/a - Recovered/Resolved -)			
EU-EC- 10012054389	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthritis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012028941	28/03/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Swelling face (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012029814	28/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Bronchitis (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10012031083	28/03/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not	COMIRNATY CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR

Run Line Listing Report

				Area					Recovered/Not Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10012031458	28/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10012031473	28/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Female	No	Syncope (20min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR

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