## Line Listing Report Time run: 30/11/2022 15:16:33

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 (D Char - Indication PT - Acti taken - [Duration - Dose - Route])
EU-EC- 10013623242	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle twitching (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013623340	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
										Musculoskeletal discomfort (n/a - Unknown - ),		
										Myalgia (n/a - Recovering/Resolving - ), Pain in extremity		
FILES	20 (00 (2022	C !	No.	F	Not a state	12.17	Child	NA - I -	NI.	(n/a - Unknown - )	COMPNIATY	EL EL LOCETTOLIZANE
EU-EC- 10013623556	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Alopecia areata (n/a - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n n/a - Oral use])
EU-EC- 10013623593	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013623787	29/09/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
			Professional	Area						Myalgia (4d - Recovered/Resolved - ),	n/a - n/a - [n/a - n/a - n/a])	
										Pyrexia (4d - Recovered/Resolved - ),		
										Rash (2d - Recovered/Resolved - )		
EU-EC- 10013623831	29/09/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
			Professional							Dysphagia (n/a - Not Recovered/Not Resolved - ),	n/a - n/a - [n/a - n/a	
										Insomnia (n/a - Unknown - ), Oropharyngeal pain		
										(n/a - Not Recovered/Not Resolved - ),		
										Secretion discharge (n/a - Not Recovered/Not Resolved - ),		
511.50	20/00/2022	Constant	li e lite		NA va Sala	12.17	Adalassan	Family	N-	Vomiting (n/a - Not Recovered/Not Resolved - ) COVID-19 (n/a -	COMPNATA	
EU-EC- 10013623835	29/09/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013623984	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),		
										Pyrexia (1d - Recovered/Resolved - )		
EU-EC- 10013624047	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Headache (0d - Recovered/Resolved - ),	, 3,	
										Malaise (n/a - Recovering/Resolving - ),		
										Myalgia (2d - Recovered/Resolved - ), Pyrexia (1d -		
										Recovered/Resolved		
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										Vaccination site pain (n/a - Recovering/Resolving - )		
J-EC- 0013624165	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
J-EC- 0013625143	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
150	20/00/2022					12.17				Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPANY	
J-EC- 0013625491	29/09/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	гетаве	No	Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										(n/a - Unknown - Other Medically Important Condition)		
U-EC- 0013626046	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
11.50	20/00/2022	Carabana	No.	5	N.A. varallable	12.17	Net	Mala	N-	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPONATO	Network
U-EC- 0013627421	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Unknown - ), Diplopia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])	
										Facial paresis (n/a - Unknown - ),		
										Headache (n/a - Unknown - ),		
										Limb discomfort (n/a		
										Recovering/Resolving - ),		
										Malaise (n/a - Unknown - ),		
										Neuralgia (n/a - Unknown - ),		
										Stridor (n/a -		
										Unknown - ), T-cell lymphoma		
										recurrent (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important		
										Condition), T-cell lymphoma stage IV (n/a - Not Recovered/Not		
										Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Testicular swelling (n/a - Unknown - ),		
										Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important		
										Condition),  Thrombosis (n/a - Unknown - Other Medically Important Condition),		
										Vomiting (n/a - Unknown - )		
:U-EC- 0013627708	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),		

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											Malaise (n/a - Not Recovered/Not Resolved - ),		
											Myalgia (n/a - Not Recovered/Not		
											Resolved - ), Nausea (n/a - Not Recovered/Not		
											Resolved - ), Vaccination site pain (n/a - Not Recovered/Not		
	EU-EC- 10013627850	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - ) Chest discomfort (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
											- ),  Dyspnoea (n/a - Recovered/Resolved	- n/a])	
											- ), Hypersensitivity (n/a		
											- Recovered/Resolved - ),		
											Palpitations (n/a - Recovered/Resolved - ),		
											Rash (n/a - Not Recovered/Not Resolved - )		
	EU-EC- 10013628256	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
											Myalgia (n/a - Not Recovered/Not Resolved - ),	- n/a])	
											Pain (n/a - Unknown - ),		
											Pain in extremity (n/a - Unknown - ),		
											Vaccination site pain (n/a - Recovering/Resolving		
											- ), Vaccination site pain		
	EU-EC- 10013628330	29/09/2022	Spontaneous		European Economic	Not available		Not Specified	Male	No	(n/a - Unknown - ) Eye pain (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S -	Not reported
					Area						Headache (n/a - Not Recovered/Not Resolved - ),	n/a - n/a - [n/a - n/a - n/a])	
											Lacrimation increased (n/a - Not Recovered/Not		
											Resolved - ),  Photophobia (n/a - Not Recovered/Not		
											Resolved - ),  Pyrexia (n/a - Not		
	EU-EC-	29/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Recovered/Not Resolved - ) Menstrual disorder		Not reported
	10013628379			Professional	Economic Area		Years	Specified			(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
	EU-EC- 10013628413	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
	EU EC	20/00/2022	Constant	Non	<u></u>	Not as a finite	12.17	Note	Mala	M-	Pain (n/a - Unknown - )	- n/a])	Not were to d
	EU-EC- 10013628496	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - ), Myalgia (1d -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
											Recovered/Resolved	1,701)	
											Pain in extremity (n/a - Unknown - ),		
											Pyrexia (2d - Recovered/Resolved - ),		
											Vaccination site pain (1d - Recovered/Resolved - )		
	EU-EC- 10013628641	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
											Dizziness (1d - Recovered/Resolved - ),	- n/a])	
											Nausea (n/a - Unknown - ),		
											Palpitations (1d - Recovered/Resolved - )		

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EU-EC- 10013628774	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628792	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628848	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip pruritus (1d - Recovered/Resolved - ), Lip swelling (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628865	29/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628886	29/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Fatigue (n/a - Recovering/Resolving - ), Lymphadenopathy (n/a - Recovering/Resolving - ), Pyrexia (1d - Recovered/Resolved	n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628965	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia universalis (399d - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013628975	29/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Recovering/Resolving	[[va - 1/a - 1/a]] [COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013629347	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013629788	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )		Not reported
EU-EC- 10013611751	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (45d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013613528	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving - ), Chills (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
EU-EC- 10013613914	28/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), Disturbance in attention (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Dyspnoea (n/a - Unknown - Disabling, Other Medically Important Condition),  Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Flatulence (136d - Recovered/Resolved - Disabling, Other Medically Important Condition),  Infection susceptibility increased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Myalgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),  Nausea (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),  Parosmia (122d - Recovered/Resolved - Disabling, Other Medically Important Condition),  Parosmia (122d - Recovered/Resolved - Disabling, Other Medically Important Condition),  Parosmia (122d - Recovered/Resolved - Disabling, Other Medically Important Condition),  Medically Important Condition)		
										Stress (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
EU-EC- 10013614619	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use])	Not reported
EU-EC- 10013616510	28/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013617147	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC- 10013617247	28/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013617435	28/09/2022	Spontaneous		European Economic Area	Pedersen, A Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013617438	28/09/2022	Spontaneous		European Economic Area	Lot. 10.3359/Lot.1202.13941. Santilli, V. Two Pediatric Cases of Multisystem Inflammatory Syndrome with Overlapping Neurological Involvement Following SARS-CoV-2 Vaccination and Unknown SARSCoV2 Infection: The Importance of Pre-Vaccination History. Vaccines. 2022;10(7):10.3390/vaccines10071136. doi:10.3390/vaccines10071136	12-17 Years	Not Specified	Female	No	Cytotoxic lesions of corpus callosum (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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										Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Life Threatening,		
										Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013617735	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013617744	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[MIDODRINE HYDROCHLORIDE] (C - Orthostatic intolerance - I [n/a - n/a - Oral use]),
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- Intramuscular use])	[PARACETAMOL] (C - Orthostatic intolerance - In/a - n/a - Oral use]),  [TAK 438] (C - Orthostati intolerance - n/a - [n/a -
										Neuralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		Oral use])
										Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013617788	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - ), Back pain (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Caused/Prolonged Hospitalisation),	- Intramuscular use])	
										Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation),		
										Electrocardiogram ST segment elevation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Electrocardiogram change (n/a - Unknown - Caused/Prolonged Hospitalisation),		
										Headache (n/a - Unknown - ),		
										Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation),		
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation,		
										Other Medically Important Condition),		

EU-EC- 10013618340 28/09,	9/2022 Spont 9/2022 Spont	taneous Non Healthcare Professional taneous Healthcare Professional	Rone Non European	Not available	Years	Specified			Recovering/Resolving - ),	immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC- 28/09,		Healthcare Professional	European Economic	Not available					Pleurisy (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving		
10013618340 EU-EC- 28/09,	9/2022 Spont					Not Specified	Ma <b>l</b> e	No	Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
			Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (0d - Recovered/Resolved - ), Headache (0d - Recovered/Resolved - ), Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]),  [INFLUENZA A VIRUS A/BRISBANE/10/2010 (HIN1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
		taneous Healthcare Professional	Economic	Sawatari, C Deep Vein Thrombosis and Pulmonary Thrombosis After BNT162bz mRNA SARSCOV2 Vaccination. Circulation Journal. 2022;86(7):1145. doi:10.1253/circj.CJ-21-1055 Ilwashima, S. A. Case of Deep Vein Thrombosis That Occurred After Vaccination with SARS-CoV2 Vaccine in a 14-year-old Male Child. The 133rd Tokai Branch Meeting of Japanese Society of Pediatric Cardiology and. 2022;133rd	Years	Specified		No	Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - ), Pulmonary embolism (n/a - Unknown - ), Pulmonary infarction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
10013618956		taneous Healthcare Professional	Area	Pedersen, A Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	Years	Specified		No	Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
10013619503	9/2022 Spont	taneous Healthcare Professional	European Economic Area	Pedersen, A Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	12-17 Years	Not Specified	Male	No	Caused/Prolonged Hospitalisation,	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
EU-EC- 28/09, 10013619732	9/2022 Spont	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	Not reported

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10013602365			Healthcare Professional			Years	Specified			consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	1{DF} -	
EU-EC- 10013602509	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013602540	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - )  Dermatitis bullous (n/a - Unknown - Other Medically Important Condition),  Papillary thyroid cancer (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(DF) - Intramuscular use])	Not reported
EU-EC- 10013602856	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Bronchitis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013602891	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urinary tract infection (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013603103	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
10013603371		Spontaneous	Professional	Economic Area	Not available	Years	Not Specified	Male	No	Aplastic anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013603518	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (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

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										Resolved - Other Medically Important Condition), Exercise tolerance		
										decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013604386	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Administration site pain (36d - Recovered/Resolved -), Body temperature	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported
										increased (12h - Recovered/Resolved - ), Headache (12h -	Intramuscular use])	
	27/09/2022	Spontaneous			Not available	12-17	Adolescent	Female	No	Recovered/Resolved - ) Administration site	COMIRNATY	Not reported
10013604835			Professional	Economic Area		Years				pain (3d - Recovered/Resolved - ), Body temperature increased (2d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	
EU-EC- 10013604846	27/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (3d -	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Area						Recovering/Resolving - ), Headache (1d -	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	
	27/09/2022	Spontaneous		European	Not available	12-17	Not	Not	No	Recovering/Resolving - ) Malaise (n/a -	COMIRNATY	Not reported
10013604884			Healthcare Professional	Economic Area		Years	Specified	Specified		Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),	1,4 1,44,5	
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),		
511.50	27/00/2000					10.17				Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013604931	27/09/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013604997	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013605307	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic	Kar, S POST COVID VACCINE ACUTE KIDNEY INJURY: A CASE REPORT. Kidney International Reports, 2022;7(9	12-17 Years	Not Specified	Male	No	Acute kidney injury (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported
				Area	Suppl):S463. doi:10,1016/j,ekir,2022,07,017					- Caused/Prolonged Hospitalisation, Other Medically Important Condition)	immunisation - Not applicable - [n/a - n/a - n/a])	
EU-EC- 10013605862	27/09/2022	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (2d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Lymphadenopathy (2d - Unknown - )	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	
EU-EC- 10013606234	27/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[iva iiva iiva])	
										Limb discomfort (n/a		
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Paraesthesia (n/a -		
										Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Tachycardia (n/a -		

										Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013606511	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013606827	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Cough (n/a - Not Recovered/Not Resolved - ), Nasal discomfort (n/a - Not Recovered/Not Resolved - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013607149	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013607222	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC- 10013607276	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Uterine pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Uterine pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{OF} - Intramuscular use])	Not reported
EU-EC- 10013607593	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013607807	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ), Somnolence (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013608092		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Fatigue (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Injection site pain (3d - Recovered/Resolved - ), Injection site reaction (3d - Recovered/Resolved - ), Injection site reaction (3d - Recovered/Resolved - ), Injection site swelling (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - n/a - Unknov [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a Unknown - [n/a - n/a - n/
EU-EC- 10013608527		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Petit mal epilepsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013610240	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a  - n/a])	Not reported
EU-EC- 10013593787		Spontaneous	Healthcare Professional	Non European	Yoshida, C A case in which improvement of COVID-19 vaccine		Not Specified	Male	No	Blood creatine phosphokinase	COMIRNATY [TOZINAMERAN] (S -	Not reported

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				Economic Area	related myocarditis could be observed on cardiac contrast MRI examination. The 133rd Kinki Branch Regular Meeting of The Japanese Circulation					increased (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COVID-19   immunisation - Not   applicable - [1d - n/a   - n/a])	
					Society, 2022;133rd:63					Chest pain (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Inflammation (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Myocarditis (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Pericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Troponin T increased (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013595164	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-	26/09/2022	Spontaneous		Non	Not available	12-17	Not	Female	No	Loss of	COMIRNATY	Not reported
10013595529				European Economic Area		Years	Specified			consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC- 10013596639	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (1d - Recovered/Resolved - ), Head discomfort (1d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Recovered/Resolved	n/a - n/a])	
										Presyncope (1d - Recovered/Resolved - ), Vision blurred (1d -		
FIL 50	26 100 12022	Constant	Non	F	No. a server de la companya de la co	12.17	Nint	M-1-	N -	Recovered/Resolved - )	COMTRNATY	Not and a
EU-EC- 10013596671	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - ), Vaccination site pain (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-	26/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Fomale	No	Recovered/Resolved - ) COVID-19 (n/a -	COMIRNATY	Not reported
10013596949	20/03/2022	Sportaneous		Economic Area	not available	Years	Adolescent	Terraic	110	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013597358	26/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013598349	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} -	Not reported
EU-EC-	26/09/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Polymenorrhoea (n/a - Unknown - ) Blood pressure	Intramuscular use]) COMIRNATY	Not reported
10013598441	, 55, 2022	,	Healthcare	Economic Area		Years				decreased (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	
										Pericarditis (n/a - Recovering/Resolving - Other Medically		
EU-EC-	26/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Important Condition) Conjunctivitis (1d -	COMIRNATY	Not reported

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10013598743			Professional	Economic Area		Years				Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	
EU-EC- 10013598762	26/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved - )	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013599744	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (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
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Injection site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Memory impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Mental impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013600286	26/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Rash (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013601088	26/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hodgkin's disease (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013601683	26/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a n/a - Oral use]), [PARACETAMOL] (C - Pain
										Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )		n/a - [n/a - n/a - Oral use
EU-EC- 10013577389	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (11mo - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [n/a -	Not reported
										- ), Rapid eye movement sleep behaviour disorder (n/a - Not Recovered/Not Resolved - Other Medically Important	Intramuscular use])	
										Condition),  Sleep attacks (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013578747	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013579022	23/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ankylosing spondylitis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INTUNIV [GUANFACINE] ( Attention deficit hyperacti disorder - n/a - [n/a - n/a Oral use]), [CALCIUM, MAGNESIUM] n/a - n/a - [n/a - n/a - n/a
										Inappropriate schedule of product administration (n/a - Unknown - ),  Juvenile idiopathic arthritis (n/a - Not		[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperacti disorder - n/a - [n/a - n/a Oral use])
										arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		

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EU-EC- 10013579675	23/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-	22/00/2022	Cooptanoous	Non	Europoan	Not available	12-17	Not	Male	No	- )	COMIRNATY	Not reported
10013579689	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Specified	Male	No	Body temperature increased (2d - Recovered/Resolved - ), Headache (2d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Recovered/Resolved		
EU-EC- 10013579732	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013579852	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ), Dyspnoea (21d - Recovering/Resolving - ), Headache (21d - Recovering/Resolving - ), Paraesthesia (21d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
EU-EC-	23/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Vaccination site pain	COMIRNATY	Not reported
10013579906		·	Professional	Economic Area		Years	Specified			(2d - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	·
EU-EC- 10013579957	23/09/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Varicella meningitis (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Area						Recovered/Resolved - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - n/a - [n/a - n/a - n/a])	
EU-EC- 10013580079	23/09/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
										Myalgia (n/a - Recovered/Resolved - )		
EU-EC- 10013580188	23/09/2022	Spontaneous		European Economic Area	Not available		Not Specified	Not Specified	No	Body temperature increased (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013580245	23/09/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Area						Irritabi <b>l</b> ity (1d - Unknown - ),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	
				_						Mood altered (1d - Unknown - )	Intramuscular use])	
EU-EC- 10013580478	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (1d - Recovered/Resolved - ), Body temperature increased (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[BETAMETHASONE DIPROPIONATE] (C - n/a n/a - [n/a - n/a - Topical]) [FUSIDIC ACID] (C - n/a - - [n/a - n/a - Topical]), [PARACETAMOL] (C - n/a n/a - [n/a - n/a - Oral use
										Eosinophilia (n/a - Recovered/Resolved - ),		, , ,
										Fatigue (1d - Recovered/Resolved - ),		
										Headache (1d - Recovered/Resolved -),		
										Myalgia (1d - Recovered/Resolved - ),		
										Rash (9d - Recovered/Resolved - )		
EU-EC- 10013580506	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (3d - Recovering/Resolving - ), Lymphadenopathy (3d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-	23/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	- ) Educational problem	COMIRNATY	Not reported
10013580588	23, 03, 2022	Sportanieous	Healthcare Professional	Economic	THE GYGINGIC	Years	Specified	Tomale		(n/a - Unknown - ), Headache (n/a - Not	[TOZINAMERAN] (S - Immunisation - n/a -	

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										Recovered/Not Resolved - Disabling),		
										Impaired quality of life (n/a - Unknown -		
EU-EC- 10013581528	23/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013581995	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported
										Autoantibody positive (n/a - Unknown - ),	[n/a - n/a - n/a])	
										Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - Disabling),		
										Coeliac disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Disturbance in attention (n/a - Not Recovered/Not Resolved - ),		
										Dizziness (n/a - Not Recovered/Not Resolved - ),		
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),		
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),		
										Food intolerance (n/a - Not Recovered/Not Resolved - ),		
										Heart rate increased (n/a - Not Recovered/Not Resolved - ),		
										Malaise (n/a - Not Recovered/Not Resolved - ),		
										Muscle spasms (n/a - Not Recovered/Not Resolved - ),		
										Nausea (n/a - Recovering/Resolving -), Post vaccination		
										syndrome (n/a - Not Recovered/Not Resolved - Disabling),		
										Weight bearing difficulty (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013582343	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	1{DF} - Intramuscular use]), [CYPROTERONE ACETATE, ETHINYLESTRADIOL]	
										Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important	(S - Contraception - Drug withdrawn - [n/a - 1{DF} - Oral use])	
										Condition),  Weight decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013582467	23/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported
										Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - Intramuscular use])	
EU-EC- 10013582563	23/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cyanosis (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported

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										Dysaesthesia (n/a - Not Recovered/Not	immunisation - Drug withdrawn - [1d - 1{DF} -	
										Resolved - )	Intramuscular use])	
EU-EC-	23/09/2022	Spontaneous	Healthcare	Non	Not available		Not	Female	No	Night sweats (n/a -	COMIRNATY	Not reported
.0013582669			Professional	European Economic		Years	Specified			Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19	
				Area							immunisation - Not	
										Pyrexia (n/a - Recovered/Resolved	applicable - [1d - n/a - n/a])	
										- ),	.,,	
										Syncope (n/a -		
										Recovered/Resolved		
										- Other Medically Important Condition)		
U-EC-	23/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Not	No	Dyspnoea (n/a -	TOZINAMERAN	Not reported
0013583909	-0,00,-0		Healthcare	European		Years	Specified	Specified		Unknown -	[TOZINAMERAN] (S -	
			Professional	Economic Area						Caused/Prolonged Hospitalisation),	COVID-19 immunisation - Not	
											applicable - [1d - n/a	
										Fall (n/a - Unknown - ),	- n/aj)	
										Heart rate decreased		
										(n/a - Unknown -		
										Caused/Prolonged		
										Hospitalisation),		
										Loss of		
										consciousness (n/a - Unknown - Other		
										Medically Important		
										Condition),		
										Neck pain (n/a -		
										Unknown - ),		
										Pain (n/a - Unknown		
										- ),		
										Vision blurred (n/a -		
										Unknown - Caused/Prolonged		
										Hospitalisation)		
U-EC- 10013583962	23/09/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S -	Not reported
0013363902			Professional	Economic		Tears	Specified			Medically Important	COVID-19	
				Area						Condition),	immunisation - Not applicable - [1d - n/a	
										Vaccination failure	- n/a])	
										(n/a - Unknown - Other Medically		
										Important Condition)		
U-EC-		Spontaneous		European	Not available		Not	Female	No	Abdominal pain (n/a	COMIRNATY	Not reported
0013584626			Healthcare Professional	Economic Area		Years	Specified			- Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	
											- n/a])	
										Chills (n/a - Recovering/Resolving		
										- ),		
										Diarrhoea (n/a -		
										Unknown - ),		
										Headache (n/a -		
										Recovering/Resolving		
										- ),		
										Malaise (n/a -		
										Unknown - ),		
										Pyrexia (n/a - Not		
										Recovered/Not Resolved - ),		
										Vaccination site erythema (n/a -		
										Recovering/Resolving		
										- ),		
										Vaccination site pain		
										(n/a - Recovering/Resolving		
										- ),		
										Vaccination site		
										pruritus (n/a -		
										Recovering/Resolving - ),		
										Vaccination site swelling (n/a -		
										Recovering/Resolving		
U-EC-	23/00/2022	Sportance	Non	Furancas	Not available	12-17	Not	Famala	No	- ) Erythema (n/a - Not	COMIRNATY	Not reported
:U-EC- :0013584693	23/09/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not	[TOZINAMERAN] (S -	Not reported
			Professional							Resolved - ),	COVID-19 immunisation - Not	
										Peripheral swelling	applicable - [n/a -	
										(n/a - Not	n/a - n/a])	
										Recovered/Not Resolved - ),		
										Pruritus (n/a - Not Recovered/Not		
										Resolved - ),		
										Rash macular (n/a -		
										Not Recovered/Not		
II EC	22/00/2022	Cnontan	Non	Europe	Not available	12.17	Not	Mala	No	Resolved - )	COMIDNATY	Not roperted
U-EC- 0013584732	23/09/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
			Professional				'				n/a - n/a - [n/a - n/a	
				1		1	I			Bone pain (n/a -	- n/a])	
		1								Recovering/Resolving		
										Recovering/Resolving - ),		

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											(n/a - Recovering/Resolving - ),		
											Dyspnoea (n/a - Unknown - ),		
											Pain in extremity		
											Pyrexia (n/a - Unknown - )		
	-EC- )13585157	23/09/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Professional	Area						Depressed mood (n/a - Unknown - ),	n/a - n/a - [n/a - n/a - n/a])	
											Nausea (n/a - Unknown - ),		
											Oropharyngeal pain		
											(n/a - Not Recovered/Not Resolved - )		
	-EC- 013585198	23/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
											Fatigue (n/a - Unknown - ),	- n/a])	
											Headache (n/a - Unknown - ),		
											Malaise (n/a - Not Recovered/Not Resolved - ),		
											Oropharyngeal pain (n/a - Unknown - ),		
FIL	-EC-	23/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Rhinorrhoea (n/a - Unknown - ) Epistaxis (28d -	COMIRNATY	Not reported
	013585201	23/03/2022	Spontaneous	Healthcare	Economic Area	Not available	Years	Specified	remale	No	Recovered/Resolved	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
	-EC- )13585277	23/09/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Professional	Area						Somnolence (n/a -	n/a - n/a - [n/a - n/a  - n/a])	
	-EC- 013585280	23/09/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported
				Professional	Area						Resolved - ), Headache (n/a - Not	n/a - n/a - [n/a - n/a - n/a])	
											Recovered/Not Resolved - ),		
											Malaise (n/a - Not Recovered/Not Resolved - ),		
											Pyrexia (n/a - Not Recovered/Not Resolved - ),		
											Vaccination site erythema (3d -		
											Recovered/Resolved		
											Vaccination site pain (2d -		
											Recovered/Resolved		
											Vaccination site pruritus (2d - Recovered/Resolved - )		
	-EC- 013585360	23/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
											Hypoaesthesia (n/a - Not Recovered/Not Resolved - ),	- n/a])	
											Malaise (n/a - Unknown - ),		
											Nausea (n/a - Not Recovered/Not Resolved - ),		
											Pyrexia (n/a - Not Recovered/Not Resolved - )		
	-EC- 013585466	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
	-EC- 013585704	23/09/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Polyarthritis (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	INTUNIV [GUANFACINE] ( Attention deficit hyperactive disorder - n/a - [n/a - n/a
					Area						Condition)	immunisation - Not applicable - [n/a - n/a - n/a])	Oral use]),  [METHYLPHENIDATE
													HYDROCHLORIDE] (C - Attention deficit hyperactiv disorder - n/a - [n/a - n/a Oral use])
	-EC- )13586452	23/09/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[FLUTICASONE PROPION/ SALMETEROL, FLUTICASC PROPIONATE, SALMETER(
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					Economic Area						Condition),  Dyspnoea (n/a -	immunisation - Not applicable - [1d - n/a - n/a])	XINAFOATE] (C - Asthma n/a - [n/a - n/a - n/a]),
											Recovered/Resolved - Other Medically Important		[PARACETAMOL] (C - Headache - n/a - [n/a - n/ n/a]),
											Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),		[SALBUTAMOL, SALBUTAM MICRONIZED, SALBUTAM SULFATE] (C - Asthma - n, [n/a - n/a - n/a])
											Headache (n/a - Recovering/Resolving - Other Medically Important Condition),		
											Hot flush (n/a - Recovered/Resolved - Other Medically Important Condition),		
											Inappropriate schedule of product administration (n/a - Unknown - ),		
											Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),		
											Tremor (n/a - Recovered/Resolved - Other Medically Important Condition),		
											Vertigo (n/a - Recovering/Resolving - Other Medically Important Condition),		
											Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)		
	EU-EC- 10013568297	22/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 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
											Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)		
	EU-EC- 10013569464	22/09/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Infection susceptibility increased (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
											Malaise (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)		
	EU-EC- 10013570068	22/09/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain lower (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
											Abnormal faeces (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
											Arthralgia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
											Decreased appetite (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
											Dizziness (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
											Ear pain (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
											Epstein-Barr virus infection (38d - Not Recovered/Not		
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										Caused/Prolonged Hospitalisation),			
										Fatigue (246d - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Headache (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Influenza (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Listless (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myalgia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Neck pain (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Sensory disturbance (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Sleep disorder (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	22/00/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Malo	No	Tachycardia (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported	
10013571486	22/03/2022	Sportaneous		Economic	Not available	Years	Adolescent	male	No	Unknown - Disabling), COVID-19 (n/a - Unknown -	[TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	
										Disabling), Chest pain (n/a - Unknown - Disabling),			
										Extrasystoles (n/a - Unknown - Disabling),			
										Fatigue (n/a - Unknown - Disabling),			
										Hyperhidrosis (n/a - Unknown - Disabling),			
										Malaise (n/a - Unknown - Disabling),			
EILEC	22/00/2222	Cnents	Hoolet	Non	Voung C. Florated to a line	12.17	No+	Eom-I	No	Myocarditis (n/a - Unknown - Disabling)	TOZINIAMEDANI	Not you t	
EU-EC-	1	Spontaneous			Young, C Elevated tacrolimus levels	12-17	INOE	Female	No	COVID-19 (n/a -	TOZINAMERAN	Not reported	18/70

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10013573353			Professional	European Economic Area	after treatment with nirmatrelvir/ritonavir (Paxlovid) for COVID-19 infection in a child with a kidney transplant Pediatr-Nephrol. 2022	Years	Specified			Recovered/Resolved - Other Medically Important Condition),  Drug ineffective (n/a - Unknown - Other	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
										Medically Important Condition)		
EU-EC- 10013573496	22/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Recovered/Not Resolved - ), Fatigue (n/a - Not	n/a - n/a])	
										Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not		
										Resolved - ),  Hypotonia (n/a - Not Recovered/Not		
										Resolved - ),  Injection site reaction (n/a - Not Recovered/Not		
										Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - ),		
										Nausea (n/a - Not Recovered/Not Resolved - ),		
										Pyrexia (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013573857	22/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013573879	22/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported
										Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])	
EU-EC- 10013574281	22/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
EU-EC-	22/09/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved - Other Medically Important Condition) Chronic fatigue	- Intramuscular use]) COMIRNATY	Not reported
10013574302	22/03/2022	Sportaneous		Economic	not available	Years	Adolescent	ridie	No	syndrome (126d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Fatigue (126d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Post viral fatigue syndrome (126d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013575097	22/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular	[DROSPIRENONE, ETHINYLESTRADIOL, LACTOSE, LACTOSE HYDROUS, LACTOSE MONOHYDRATE] (C -
										C-reactive protein increased (n/a - Unknown - ),	use])	Dysmenorrhoea - n/a - [i n/a - Oral use])
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Motor dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										White blood cell count increased (n/a - Unknown - )		
EU-EC- 10013576203	22/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved - ), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

0-EC- 0013557082	21/03/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	IRON [IRON] (C - n/a ), [THIAMINE
U-EC-	21/00/2022	Spontons	Non	Furance	Not available	12.17	No+	Famala	Ma	- Unknown - ), Wheelchair user (n/a - Unknown - )	COMIDNATY	TPON FEDONIA CO 1
										Speech disorder (n/a - Not Recovered/Not Resolved - ), Supportive care (n/a		
										Pyrexia (n/a - Unknown - ),		
										Photophobia (n/a - Unknown - ),		
										Nasopharyngitis (n/a - Unknown - ),		
										Muscle spasms (n/a - Not Recovered/Not Resolved - ),		
										independence in daily activities (n/a - Unknown - ),		
										Unknown - ), Loss of personal		
										- Not Recovered/Not Resolved - ), Listless (n/a -		
										- ), Initial insomnia (n/a		
										Resolved - ),  Illness (n/a - Recovered/Resolved		
										Hyperventilation (n/a - Not Recovered/Not		
										Resolved - ),  Hyperacusis (n/a - Unknown - ),		
										Headache (n/a - Not Recovered/Not		
										Gait disturbance (n/a - Not Recovered/Not Resolved - Disabling),		
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),		
										Not Recovered/Not Resolved - ), Fatigue (n/a - Not		
										Recovered/Not Resolved - ), Eyelid ptosis (n/a -		
										Dysphonia (n/a - Unknown - ), Dyspnoea (n/a - Not	immunisation - Not applicable - [1d - n/a - n/a])	
-EC- 013556833	21/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bedridden (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Menstruation irregular (n/a - Recovered/Resolved - Other Medically Important Condition)		
										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])	
-EC- 013556657	21/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Unknown - ), Menstruation delayed	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
013576292			Professional			Years				(n/a - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
-EC-	22/09/2022	Spontaneous			Not available		Adolescent	Female	No	Injection site pain	withdrawn - [1d - .3mL - Intramuscular use]) COMIRNATY	Not reported
I-EC- 013576222	22/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported
										- ), Pyrexia (n/a - Recovered/Resolved		
										Pain in extremity (n/a - Recovered/Resolved		
										- ),	n/a - n/a])	

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										Educational problem (n/a - Unknown - ),		HYDROCHLORIDE, RETIN (C - n/a - n/a - )
										Heavy menstrual bleeding (n/a - Recovering/Resolving - ),		
										Mineral supplementation		
EU-EC-	21/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	(n/a - Unknown - ) Chest discomfort	COMIRNATY	Not reported
10013557176			Healthcare	European Economic Area		Years	Specified			(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a - n/a])	
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Hyperhidrosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation,		
										Other Medically Important Condition)		
EU-EC- 10013557271	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Recovering/Resolving - ),		
										Lymphadenopathy (n/a - Recovering/Resolving		
										- ), Pyrexia (n/a - Recovering/Resolving		
EU-EC- 10013557604	21/09/2022	Spontaneous	Non Healthcare	Non European	Not available		Not Specified	Female	No	- ) Dizziness (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S -	Not reported
			Professional	Economic Area						- ), Syncope (1d - Recovered/Resolved - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
										Vision blurred (n/a - Unknown - )		
EU-EC- 10013557691	21/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Insomnia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C-Muscle spasms - n/a - [n/a n/a - n/a]),  [PARACETAMOL] (C - Pain n/a - [n/a - n/a])
EU-EC- 10013557728	21/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID PH. EUR PARACETAMOL PH. EUR.] Rhinorrhoea - n/a - [n/a - - n/a]), [PARACETAMOL] (C -
										Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		Oropharyngeal pain - n/a [1d - n/a - n/a])
										Dehydration (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013558221	21/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Female	No	Candida infection (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMOXICILLIN, AMOXICIL TRIHYDRATE] (C - Urinary tract infection - n/a - [n/a n/a - n/a]), [FLUCONAZOLE] (C - Canc
										Urinary tract infection (n/a - Recovering/Resolving	.,,u])	infection - n/a - [n/a - n/a n/a])

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										- Other Medically Important Condition),		
										Vulvovaginal candidiasis (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013558232	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved - Disabling),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Hormone level abnormal - - [n/a - n/a - n/a]),
										Abdominal pain (n/a - Unknown - Disabling),	- n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Hypothyroidism - n/a [n/a - n/a - n/a])
										Chills (n/a - Recovering/Resolving - Disabling),		
										Dizziness (n/a - Recovering/Resolving - Disabling),		
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),		
										Headache (n/a - Recovering/Resolving - Disabling),		
										Insomnia (n/a - Unknown - Disabling),		
										Myalgia (n/a - Not Recovered/Not Resolved - Disabling),		
										Nausea (n/a - Recovering/Resolving - Disabling),		
										Retching (n/a - Recovering/Resolving - Disabling),		
										Vomiting (2d - Recovered/Resolved With Sequelae - Disabling)		
EU-EC- 10013559678	21/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[CEFATRIZINE PROPYLENI GLYCOL] (C - Rhinitis - n/a [n/a - n/a - n/a]), [DROSPIRENONE,
										Influenza (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),	- n/a])	ETHINYLESTRADIOL, ETHINYLESTRADIOL, LEVONORGESTREL] (C - Hormone level abnormal - [n/a - n/a - n/a])
										Influenza like illness (n/a - Unknown - Disabling, Other Medically Important Condition),		
										Nasopharyngitis (n/a - Unknown - Disabling, Other Medically Important Condition),		
										Pyrexia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)		
EU-EC- 10013559799	21/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gastroenteritis (n/a - Unknown - ), Urinary tract	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
				Arca						infection (n/a - Unknown - ),	applicable - [1d - n/a - Intramuscular use])	
										Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013560313	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash macular (8d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Recovered/Resolved - ),	applicable - [n/a - n/a - n/a])	
EU-EC-	21/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Skin disorder (8d - Recovered/Resolved - ) Fatigue (n/a - Not	COMIRNATY	Not reported
10013560947	21/03/2022	Sportaneous	Healthcare Professional	Economic	THE GYANGON	Years	Specified	i-ialC	140	Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	not reported
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - n/a - n/a])	
										Myalgia (n/a - Not Recovered/Not Resolved - )		

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EU-EC- 10013561645	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Vaccination site pruritus (n/a - Unknown - Other Medically Important Condition),		
										Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013561985	21/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site reaction (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Myalgia (n/a - Not Recovered/Not		
EU-EC- 10013563029	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - )  Menometrorrhagia (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Drug	Not reported
										, ,	1{DF} - Intramuscular use])	
EU-EC- 10013563198	21/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013564416	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Chills (n/a - Recovering/Resolving - ),	1,741)	
										Headache (n/a - Recovering/Resolving - ),		
										Vomiting (n/a - Recovering/Resolving - )		
EU-EC- 10013564532	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Dizziness (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	CIRCADIN [MELATONIN] n/a - n/a - [n/a - n/a - Or use]),
										Recovered/Not Resolved - ),	.,, 2])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n [n/a - n/a - Oral use]),
										Malaise (n/a - Not Recovered/Not Resolved - ),		[MELATONIN] (C - n/a - n [n/a - n/a - Oral use]),
										Nausea (n/a - Not Recovered/Not Resolved - )		[SERTRALINE] (C - n/a - r [n/a - n/a - Oral use])
EU-EC- 10013564612	21/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal behaviour (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013564625	21/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ),	COMIRNATY	Not reported
										Fatigue (n/a - Not Recovered/Not Resolved - ),	- n/a])	
										Headache (n/a - Not Recovered/Not Resolved - ),		
										Malaise (n/a - Not Recovered/Not Resolved - ),		
										Nausea (n/a - Not Recovered/Not Resolved - ),		
										Pain (n/a - Not Recovered/Not Resolved - ),		
										Pyrexia (n/a - Not Recovered/Not Resolved - ),		
										Vaccination site pain (n/a - Not Recovered/Not Resolved - ),		
										Vaccination site swelling (n/a - Not Recovered/Not		
EU-EC-	21/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Resolved - ) Lymphadenopathy	COMIRNATY	Not reported

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10013564982			Healthcare Professional			Years	Specified			(n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
										Swelling (n/a - Unknown - )		
EU-EC- 10013565112	21/09/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
			Professional	Area						Headache (n/a - Unknown - ),	n/a - n/a - [n/a - n/a - n/a])	
										Insomnia (n/a - Unknown - ),		
										Malaise (n/a - Not Recovered/Not Resolved - ),		
										Pain (n/a - Recovering/Resolving - ),		
511 50	24 /00 /2022			_		10.17				Pyrexia (n/a - Unknown - )	- COMPANY	
EU-EC- 10013565188	21/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Taste disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013565232	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013566230	21/09/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE] (C - n/a - - [n/a - n/a - Inhalation us [SALBUTAMOL, SALBUTAN SULFATE] (C - n/a - n/a -
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		- n/a - n/a]), [TRANEXAMIC ACID] (C - - n/a - [n/a - n/a - Oral us
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition),		
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013566327	21/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013566959	21/09/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										- ), Myalgia (1d - Recovered/Resolved - ),		
										Nausea (0d - Recovered/Resolved - ),		
										Pyrexia (1d - Recovered/Resolved - ),		
										Vomiting (0d - Recovered/Resolved		
EU-EC- 10013546098	20/09/2022	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
				Area						- ), Chest pain (n/a - Recovered/Resolved	immunisation - Not applicable - [1d - n/a - n/a])	
										- ), Dyspnoea exertional		
										(n/a - Recovered/Resolved		
										Palpitations (n/a - Recovered/Resolved		
										- ), Pericarditis (n/a -		
										Recovered/Resolved - Other Medically		
EU-EC- 10013546241	20/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported

	2010-1-					15		_		Medically Important Condition)		
EU-EC- 10013546963	20/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013547482	20/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition),		
										Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
:U-EC- 0013547708	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	. 3	
										Eye pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
	20/00/2022		New	Non		12.17	New		Ma	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMINATO	Networked
:U-EC- 0013548005	20/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Renal failure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
:U-EC- .0013548070	20/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported
										Orthostatic intolerance (n/a - Not Recovered/Not Resolved - ), Syncope (n/a - Not	Intramuscular use])	
	20/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Recovered/Not Resolved - Other Medically Important Condition) Fatigue (n/a -	COMIRNATY	Not reported
.0013549004			Healthcare	Economic Area		Years	Specified				[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	

										Recovering/Resolving - ), Injection site reaction (n/a -		
										Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving		
										- ), Nausea (n/a - Recovering/Resolving - ),		
										Pyrexia (n/a - Recovering/Resolving - ),		
										Skin disorder (n/a - Recovering/Resolving - )		
EU-EC- 10013549908	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (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
EU-EC- 10013551048	20/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013551115	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013551143	20/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FLUTICASONE PROPION. SALMETEROL, FLUTICASC PROPIONATE, SALMETER XINAFOATE] (C - Asthma n/a - [n/a - 2{DF} - Inhalation use]), [SALBUTAMOL, SALBUTAN SULFATE] (C - Asthma - n
										Circulatory collapse (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[n/a - n/a - Inhalation uso
										Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013551153	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	7,21	
										Pyrexia (n/a - Unknown - Other Medically Important Condition),		
EU-EC-	20/00/2022	Chartenassia	Non	Furences	Not veileble	12.17	Not	Formula	No	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY	Net reported
10013551952	20/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ), Heavy menstrual bleeding (n/a - Unknown - ),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Heavy menstrual bleeding (n/a - Unknown - Disabling),		
										Menstruation irregular (n/a - Unknown - ), Red blood cell count decreased (n/a -		
EU-EC- 10013552300	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported

											withdrawn - [1d - 1{DF} -	
EU-EC- 10013552813	20/09/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),  Drug ineffective (n/a - Unknown - Other	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Medically Important Condition)		
EU-EC- 10013554801	20/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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
										Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)		
EU-EC- 10013555100		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported
EU-EC- 10013536838	19/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Recovering/Resolving - Other Medically Important Condition),		
										Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),		
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),		
FIL FC	10/00/2022		Non	F.,,,,,,,,,,	Net and letter	12.17	Adelessan	Famala	No	Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY	Nebvenested
EU-EC- 10013537292	19/09/2022	Spontaneous	Healthcare Professional	Economic	Not available	Years	Adolescent	remale	No	Application site pruritus (n/a - Not Recovered/Not Resolved - ), Injection site	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										urticaria (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013537640	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013538410	19/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	-1-3/	
				1		1	I	I	1	Inappropriate	1	I
										schedule of product administration (n/a - Unknown - ), Lethargy (n/a - Not		

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										Medically Important Condition),		
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
EU-EC-	19/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition) Myocarditis (n/a -	COMIRNATY	Not reported
10013538518	15,05,2022	Sportaricous	Healthcare	European Economic Area	THE GVINDSE	Years	Specified	ridic		Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	not reported
EU-EC- 10013538820	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Myalgia (n/a - Recovered/Resolved - ),		
										Nausea (n/a - Recovered/Resolved - ), Presyncope (n/a -		
										Recovered/Resolved - ), Pyrexia (64d - Recovered/Resolved		
EU-EC-	19/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Adult	Female	No	- ) Body temperature	COMIRNATY	Not reported
10013539121			Professional	Economic Area		Years				increased (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	
EU-EC- 10013539314	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10 (8):10,3390/vaccines10081207, doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013539479	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10 (8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013539548	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013539901	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (31d - Recovering/Resolving - ), Pyrexia (31d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013540220	19/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (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
EU-EC- 10013540970	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Cardiac valve sclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported
										Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Dyspnoea (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Fatigue (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation,		

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										Other Medically Important Condition),		
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Palpitations (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013541063	19/09/2022	Spontaneous		Non European Economic Area	Aviel, Y Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study Vaccines, 2022;10(8):10,3390/vaccines10081207, doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013541065	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Cole, L Multisystem Inflammatory Syndrome after Breakthrough SARS- CoV-2 Infection in 2 Immunized Adolescents, United States. Emerging Infectious Diseases, 2022;28(7):1456- 1459. doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Male	No	Breakthrough COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-	10/00/2022	Spontaneous	Llogithopyo	Non	Net sucileble	12-17	Not	Mala	No	Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition) Breathing-related	COMIRNATY	Not reported
10013541097	19/09/2022	Sportaneous		European Economic Area	Not available	Years	Specified	Male	NO	sleep disorder (9d - Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Chest pain (9d - Recovered/Resolved - ), Cough (9d -	- n/a])	
										Recovered/Resolved - ), Haematemesis (9d -		
										Recovered/Resolved - Other Medically Important Condition),		
										Palpitations (9d - Recovered/Resolved - ),		
										Wheezing (9d - Recovered/Resolved - )		
EU-EC- 10013541242	19/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Lethargy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013541387	19/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Dyspnoea (n/a - Not Recovered/Not Resolved - ), Loss of	applicable - [1d - n/a - n/a])	
										consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important		

REACT   1990-2003   Sentances   Madistrate   National Projects and P		1.2022	10.17					i (dii	LING LIS	ung rto	port			
Part												Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - )		
B1-67			19/09/2022	Spontaneous		European Economic	Following COVID-19 Vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and			Male	No	(n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
RI-SC   19/09/2022   Speriamental Predictioner   Not provided   19/09/2022   Speriamental Predictioner   Not provided   19/09/2022   Speriamental Predictioner   Not provided   Not prov												(n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important		
EU-EC   19(0),00022   Sportamentus   Pentinorae   More analysis   Sportamentus   Pentinorae   Sportamentus   Pentinorae   Sportamentus   Pentinorae   Pentinora												Troponin I increased		
	EU 10	-EC- 013542135	19/09/2022	Spontaneous		European	Not available			Female	No		[TOZINAMERAN] (S -	Not reported
EU-EC-   19/99/2022   Spontamenus   Num   Industrians   Communication   Num   Industrians   Communic						Area						Unknown - Life Threatening),	applicable - [1d - n/a	
E1-E2-   19/09/2022   Sportaneous   Non   European   Not available   12-17   Addescent   Female   No.   Secure   No.   No.   No.   Reported   19/09/202   Sportaneous   Non   Repo												Unknown - Life Threatening),		
			10/00/2022					10.17				(n/a - Unknown - Other Medically Important Condition)	COMPLIAN.	
ELL-EC- 10013542495   Spontaneous   Non Healthcare   European Professional   E			19/09/2022	Spontaneous	Healthcare	Economic	Not available		Adolescent	remale	NO	bleeding (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported
EU-EC- 10013542693   19/09/2022   Spontaneous   Healthcare   European Professional   Area   Not available   12-17   Adolescent   Female   Not   Menstruation delayed (n/a - Not   Recovered/jbot   Recovered/jbo												Recovering/Resolving Other Medically		
Frofessional   Economic Area   Professional   Economic Area   Professional   Economic Area   Professional   Economic Area   Professional   Professional   Economic Area   Professional			19/09/2022	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported
Healthcare   Professional   Profes			19/09/2022		Professional	Economic	Not available		Adolescent	Female	No	(n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported
EU-EC- 10013543857  19/09/2022 Spontaneous Healthcare Professional European Economic Area Street of Professional Ferrores Street			19/09/2022	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	Recovering/Resolving ), Menstruation delayed (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported
Professional European Element   Professional European   Following mRNA COVID Vaccine   Vears   Specified   Professional   Recovered/Resolved   Caused/Prolonged Hospitalisation, other medically   Important Condition   OVID-19   Important Condition   Ovi	EU	-EC-	19/09/2022	Spontaneous	Healthcare	Non	Aviel, Y., Case Series of Myocarditis	12-17	Not	Male	No	-)	TOZINAMERAN	Not reported
Healthcare Professional Area  Non Healthcare Professional Area  Not available 12-17 Years  Not Wale Non Hyperhidrosis (n/a - Not Applicable - [n/a - n/a])  EU-EC- 10013535193  Not available 12-17 Not Specified Not Wale Non Hyperhidrosis (n/a - Not Applicable - [n/a - n/a])  Not reported (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a])  Not reported (TOZINAMERAN) (S - COVID-19 immunisation)			, ,	·		European Economic	Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study. Vaccines, 2022;10 (8):10.3390/vaccines10081207.					Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	·
EU-EC- 1013545227  EU-EC- 1013535193  EU-EC- 1013535193  EU-FC- 1013535193  Recovered/Resolved - )  Not available  12-17 Years  Adolescent Female 12-17 Years  Adolescent Female No Headache (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Resolved - (COVID-19) Immunisation - Not applicable - [n/a - 1{OFI} - n/a])  Not reported  COMIRNATY Years  Not available  12-17 Years  Professional  No Hyperhidrosis (n/a - Recovered/Resolved - ),  COMIRNATY (TOZINAMERAN] (S - COVID-19 Immunisation - ITOZINAMERAN] (S - COVID-19 Immunisation - ITOZINAMERAN] (S - COVID-19 Immunisation -			19/09/2022	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
EU-EC- 1013545227  EU-EC- 10013545227  EU-EC-												Recovered/Resolved - ), Pyrexia (n/a -		
Professional Area  Professional			19/09/2022	Spontaneous			Not available		Adolescent	Female	No	- ) Headache (n/a - Not		Not reported
EU-EC- 17/09/2022   Spontaneous   Non Healthcare   Frofessional   Area   European   Not available   12-17   Years   Specified   Specified   No Hyperhidrosis (n/a - Recovered/Resolved   17/09/2022   Recovered/Re	100	J1354522/						rears				Resolved - Caused/Prolonged	COVID-19 immunisation - Not applicable - [n/a -	
Loss of			17/09/2022	Spontaneous	Healthcare	Economic	Not available			Male	No	Recovered/Resolved - ), Loss of consciousness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported

										- Other Medically Important Condition)		
EU-EC- 10013535214	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013535377	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nephritic syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013535489	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acne (n/a - Recovered/Resolved - ), Asthenia (n/a - Recovered/Resolved - ), Electrocardiogram T wave inversion (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
										- Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - ),		
										Pyrexia (n/a - Recovered/Resolved - ), Skin depigmentation (n/a - Recovered/Resolved		
	17/09/2022	Spontaneous		European	Not available	12-17	Not	Male	No	- ) Malaise (n/a -	COMIRNATY	Not reported
10013535532			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving - ),  Muscle fatigue (n/a - Recovering/Resolving - ),	COVID-19 immunisation - n/a - [n/a - 30ug -	
										Tachycardia (n/a - Recovering/Resolving		
EU-EC- 10013524590	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a	[LYMECYCLINE] (C - Acn n/a - [n/a - n/a - n/a])
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])	
										Pain in extremity (3d		
EU-EC- 10013524948	16/09/2022	Spontaneous	Non Healthcare	Non European	Not available		Not Specified	Female	No	Recovered/Resolved - Other Medically Important Condition) Abdominal pain (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S -	Not reported
			Professional	Economic Area			·			Resolved - Other Medically Important Condition), Anaemia (n/a -	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
										Recovering/Resolving - Other Medically Important Condition),		
										Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Constipation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Deafness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other		

										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lower respiratory tract infection (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Productive cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Taste disorder (n/a - Not Recovered/Not Resolved - Other Medically Important		
EU-EC- 10013525145	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Hypoaesthesia (n/a - Recovering/Resolving - ),  Product administered to patient of inappropriate age (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID- 19 VACCINE ASTRAZENECA	Not reported
EU-EC- 10013525687	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Tremor (n/a - Recovering/Resolving - ) Body temperature increased (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
EU-EC- 10013525694	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (2d - Recovering/Resolving - ), Headache (3d - Recovering/Resolving	immunisation - Not applicable - [n/a - 1{DF} -	Not reported
EU-EC- 10013526714	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013526812		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [ (S - [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL FUMARATE] - Hypertrophic cardiomyopathy - n/a - [n, n/a - n/a])
EU-EC- 10013527102	16/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

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										Condition), Tremor (n/a - Unknown - Other Medically Important		
U-EC- 0013527235	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition)  Administration site pain (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Body temperature increased (1d - Recovered/Resolved -)	1{DF} - Intramuscular use])	
U-EC- 0013527261	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Arthralgia (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported
										Headache (n/a - Unknown - ),	Intramuscular use])	
										Myalgia (n/a - Unknown - )		
EU-EC- 0013527883	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	- n/a])	
EU-EC- .0013528030	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (143d - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Angina pectoris (148d - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Angina pectoris (155d - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Arrhythmia (143d - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Arrhythmia (155d - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Dyspnoea (143d - Not Recovered/Not Resolved - ),		
										Dyspnoea (148d - Not Recovered/Not Resolved - ),		
										Dyspnoea (155d - Not Recovered/Not Resolved - )		
EU-EC- 10013528210	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (27d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	[n/a - n/a - n/a])	
EU-EC- 10013528341	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye pain (59d -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Headache (31d - Recovered/Resolved - ),	immunisation - n/a - [n/a - n/a - n/a])	
										Myalgia (71d - Recovering/Resolving		
EU-EC- 10013528364	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Disorientation (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Dizziness (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Fatigue (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Headache (236d - Not Recovered/Not		

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										Resolved - Caused/Prolonged Hospitalisation),		
										Muscle atrophy (236d - Not Recovered/Not Resolved -		
										Caused/Prolonged Hospitalisation),		
										Pyrexia (236d - Not Recovered/Not Resolved - Caused/Prolonged		
EU-EC- 10013528566	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breakthrough COVID-19 (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported
										Fatigue (n/a - Not Recovered/Not Resolved - ),	[n/a - n/a - n/a])	
										Infection susceptibility increased (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013528806	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Psychotic disorder (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - n/a - n/a])	
										Suicidal ideation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013529368	16/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[MEFENAMIC ACID] (C - Dysmenorrhoea - n/a - [n, n/a - n/a])
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013529819	16/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - ), Lethargy (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Post-acute COVID-19 syndrome (n/a - Unknown - Other Medically Important Condition)	n/a - n/a])	
EU-EC- 10013530403	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Menstruation delayed (n/a - Not Recovered/Not Resolved - ),	2{DF} - Intramuscular use])	
										Vulvovaginal mycotic infection (n/a - Recovered/Resolved - )		
EU-EC- 10013530515	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (30d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Intermenstrual bleeding (30d - Recovered/Resolved - )	immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	
EU-EC- 10013531221	16/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013531314	16/09/2022	Spontaneous		Non European Economic Area	Hirai, Y A case of myopericarditis in a 15-year-old boy following mRNA coronavirus disease 2019 vaccination. Japanese Journal of Pediatrics. 2022;75(4):627-632	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[A/HONG KONG/4801/201 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201 X-263B), B/BRISBANE/60/2008-LIK
										Hospitalisation),  Chest pain (n/a - Recovered/Resolved - Caused/Prolonged	- Intramuscular use])	STRAIN (B/BRISBANE/60/2008, W TYPE), A/CALIFORNIA/7/2 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-18
										Hospitalisation), Electrocardiogram ST		A/HONG KONG/4801/201 <sup>2</sup> (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201
										segment elevation (n/a - Recovered/Resolved		X-263B), B/BRISBANE/60/2008-LIK STRAIN
										- Caused/Prolonged Hospitalisation, Other Medically Important Condition),		(B/BRISBANE/60/2008, W TYPE), A/MICHIGAN/45/2I (H1N1)PDM09-LIKE STRAI (A/SINGAPORE/GP1908/2I IVR-180), INFLUENZA
										Electrocardiogram T wave inversion (n/a -		VACCINE] (C - Immunisati n/a - [n/a - n/a - Subcutaneous use])

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											Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving		
											- Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important		
											Condition),  Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
											Troponin T increased (n/a - Recovering/Resolving - Caused/Prolonged		
											Hospitalisation),  Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
	EU-EC-	16/00/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported
	10013532176	10/09/2022	Sportaneous		Economic	NUL available		Specified	remale		Cold sweat (n/a - Unknown - ), Dizziness (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
											Illness (n/a - Unknown - ),		
											Pain in extremity (n/a - Not Recovered/Not Resolved - ),		
											Pyrexia (n/a - Not Recovered/Not Resolved - ),		
											Vomiting (n/a - Not Recovered/Not Resolved - )		
	EU-EC- 10013532596	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Important - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain in (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Medically Important Medically Important Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
		16/09/2022		Healthcare Professional	European Economic	Not available			Male	No	Recovered/Not Resolved - ) Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Palin in extremity (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
	10013532596			Healthcare Professional	European Economic	Not available		Specified		No	Recovered/Not Resolved - )  Dizziness (n/a - Unknown - Other Medically Important Condition),  Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Influenza like illness (n/a - Unknown - Other Medically Important Condition),  Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition),  Pain (n/a - Unknown - Other Medically Important Condition),  Pain in extremity (n/a - Unknown - Other Medically Important Condition),  Pain in extremity (n/a - Unknown - Other Medically Important Condition),  Pallor (n/a - Unknown - Other Medically Important Condition),  Syncope (n/a - Unknown - Other Medically Important Condition),  Syncope (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
	10013532596			Healthcare Professional	European Economic Area	Not available  Not available	12-17	Specified		No	Recovered/Not Resolved - )  Dizziness (n/a - Unknown - Other Medically Important Condition),  Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Influenza like illness (n/a - Unknown - Other Medically Important Condition),  Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition),  Pain (n/a - Unknown - Other Medically Important Condition),  Pain (n/a - Unknown - Other Medically Important Condition),  Pain in extremity (n/a - Unknown - Other Medically Important Condition),  Pallor (n/a - Unknown - Other Medically Important Condition),  Pallor (n/a - Unknown - Other Medically Important Condition),  Syncope (n/a - Unknown - Other Medically Important Condition),  Vaccination site haemorrhage (n/a - Unknown - Other Medically Important Condition)  Dysphonia (n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported  Not reported

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										- Caused/Prolonged Hospitalisation),		
										Pain in extremity		
										(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC- 10013532615	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - ), Rash (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU EC	16/00/2022	Cnontangous	Non	Europoan	Not available	12-17	Not	Fomalo	No	Recovered/Not Resolved - )	COMIDNATY	Not reported
EU-EC- 10013532737	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Specified	Female	No	Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Vaccination site pain (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013532757	16/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Chills (n/a - Not Recovered/Not Resolved - ),	- I(/a])	
										Fatigue (n/a - Not Recovered/Not Resolved - ),		
										Headache (n/a - Not Recovered/Not Resolved - ),		
										Myalgia (n/a - Not Recovered/Not Resolved - ),		
										Pain (n/a - Not Recovered/Not Resolved - ),		
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),		
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EU-EC- 10013533092	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - ), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Resolved - ),  Malaise (n/a - Not Recovered/Not		
										Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not		
										Resolved - ), Pain (n/a - Unknown - ),		
										Vaccination site pain (n/a - Recovering/Resolving		
EU-EC- 10013533137	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
EU-EC- 10013533400	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
										Vaccination failure (n/a - Unknown - Other Medically	and an use j	
EU-EC- 10013533591	16/09/2022	Spontaneous		European Economic	Not available		Not Specified	Male	No	Important Condition) Chest discomfort (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S -	Not reported
10013533591			Healthcare Professional			Years	эрестеа			(n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S -   n/a - n/a - [n/a - n/a   - n/a])	
										Fatigue (n/a - Not Recovered/Not Resolved - Other		

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										Medically Important Condition), Heart rate increased (n/a - Unknown - Other Medically Important Condition),		
										Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition),		
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013534019	16/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013534043	16/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013534075	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported
EU-EC- 10013513795	15/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysarthria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Expired product administered (n/a - Unknown - ), Headache (n/a -	- Intramuscular use])	
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a -		
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory loss (n/a -		
FILE C	15/00/2022	Constant	None	Nan	No. 1 and 1	12.17	Note	FI-	NI-	Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMEDANI	Neberseded
EU-EC- 10013514313		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013515265	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Body temperature increased (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013515460	15/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site erythema (36h - Recovered/Resolved - ), Administration site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported
										oedema (36h - Recovered/Resolved - ), Body temperature	Intramuscular use])	
										increased (1d - Recovered/Resolved - ),		
										Chest pain (8h - Recovered/Resolved - ), Dyspnoea (8h -		
										Recovered/Resolved - ), Myalgia (1d - Recovered/Resolved		
EU-EC- 10013515687	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Monoplegia (3d - Recovered/Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[PARACETAMOL] (C - Headache - n/a - [n/a - n/ n/a]),
				, , , ,						Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])	[SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - n/ n/a - [n/a - n/a - n/a])
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important		

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										Condition),		
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically		
	15/09/2022	Spontaneous		Non	Not available	12-17	Not	Female	No	Important Condition) Dizziness (n/a -	TOZINAMERAN	[ETHINYLESTRADIOL,
10013515694			Healthcare Professional			Years	Specified			Recovered/Resolved - Disabling),	COVID-19	LEVONORGESTREL] (C - Dizziness, Dysmenorrhoe
				Area						Dysmenorrhoea (n/a - Not Recovered/Not	immunisation - Not applicable - [1d - n/a	n/a - [n/a - n/a - n/a])
										Resolved - Disabling),	- 11/d])	
										Heavy menstrual		
										bleeding (n/a - Not Recovered/Not		
:U-EC-	15/09/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Resolved - Disabling) Blood pressure	COMIRNATY	Not reported
10013515776	,,		Professional	European Economic		Years	Specified			diastolic increased (n/a - Unknown -	[TOZINAMERAN] (S - COVID-19	
				Area						Other Medically Important	immunisation - Not applicable - [1d - n/a	
										Condition),	- Intramuscular use])	
										Dizziness (n/a - Recovering/Resolving - Other Medically		
										Important Condition),		
										Heart rate increased		
										(n/a - Unknown - Other Medically		
										Important Condition),		
										Mycoplasma test		
										positive (n/a - Unknown - Other		
										Medically Important Condition),		
										Pyrexia (19d - Recovered/Resolved		
										- Other Medically Important		
										Condition),		
										Vomiting (n/a - Recovering/Resolving		
										- Other Medically Important Condition)		
EU-EC- 10013516061	15/09/2022	Spontaneous		Non European	Not available		Not Specified	Male	No	Peripheral swelling (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported
			Professional	Area						Resolved - Life Threatening,	immunisation - Not applicable - [n/a -	
										Caused/Prolonged Hospitalisation,	n/a - n/a])	
										Disabling),		
										Surgery (n/a - Unknown - Life		
										Threatening, Caused/Prolonged		
										Hospitalisation, Disabling, Other		
										Medically Important Condition),		
										Thrombosis (n/a - Not Recovered/Not		
										Resolved - Life Threatening,		
										Caused/Prolonged Hospitalisation,		
										Disabling, Other Medically Important		
	15/09/2022	Spontaneous		Non	Not available		Not	Female	No	Condition) Inappropriate	TOZINAMERAN	Not reported
10013518564				European		Years	Specified			schedule of product	[TOZINAMERAN] (S - COVID-19	
			Professional							administration (n/a -		
			Professional	Area						Unknown - ),	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ), Insomnia (n/a - Not Recovered/Not	immunisation - Not	
			Professional							Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a -	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown - ),	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Cyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a	
			Professional							Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not	immunisation - Not applicable - [1d - n/a	
	15/09/2022	Spontaneous	Healthcare	Non European	Arai, S A Case of Acute Myocarditis After SARS-CoV-2 Vaccination. The 58th		Not Specified	Male	No	Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])  COMIRNATY TOZINAMERAN1 (S -	Not reported
	15/09/2022	Spontaneous	Healthcare	Area	After SARS-CoV-2 Vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac.			Male	No	Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Resolved - Other Medically Important Condition)  Chest pain (n/a - Unknown - ),  Electrocardiogram ST	immunisation - Not applicable - [1d - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
	15/09/2022	Spontaneous	Healthcare	Non European Economic	After SARS-CoV-2 Vaccination. The 58th Annual Meeting of Japanese Society of			Male	No	Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  Chest pain (n/a - Unknown - ),  Electrocardiogram ST segment elevation (n/a - Unknown - )	immunisation - Not applicable - [1d - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
	15/09/2022	Spontaneous	Healthcare	Non European Economic	After SARS-CoV-2 Vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac.			Male	No	Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  Chest pain (n/a - Unknown - ),  Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Other Medically Important Punknown - Other Medically Important Medically I	immunisation - Not applicable - [1d - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
EU-EC- 10013519583	15/09/2022	Spontaneous	Healthcare	Non European Economic	After SARS-CoV-2 Vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac.			Male	No	Unknown - ),  Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Off label use (n/a - Unknown - ),  Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  Chest pain (n/a - Unknown - ),  Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Unknown - Other Medically	immunisation - Not applicable - [1d - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported

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										(n/a - Unknown - Other Medically Important Condition),		
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
										Pyrexia (n/a -		
EU-EC-	15/09/2022	Spontaneous	Healthcare	Non	Not available		Not	Female	No	Unknown - ) Chest pain (n/a - Not		Not reported
10013519849			Professional	European Economic Area		Years	Specified			Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	
										Suffocation feeling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- n/a])	
EU-EC- 10013520167	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported
EU-EC-	15/09/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	- ) Heavy menstrual	Intramuscular use]) COMIRNATY	Not reported
10013520204			Healthcare Professional	Economic Area		Years				bleeding (n/a - Recovering/Resolving - ), Oligomenorrhoea	immunisation - Not applicable - [n/a - n/a - Intramuscular	
										(n/a -   Recovering/Resolving  - )	use])	
EU-EC- 10013520237	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	[LACTULOSE, PARAFFIN WHITE SOFT, LIQUID PARAFFIN, LACTULOSE, VASELINE, LIQUID PARAFFIN] (C - n/a - n/a [n/a - n/a - n/a]),
											initianiusculai usej)	[TRIMEBUTINE] (C - n/a - - [n/a - n/a - n/a])
EU-EC- 10013520310	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	[PHLEUM PRATENSE (225 (C - n/a - n/a - [n/a - n/a n/a])
										Seizure (1d - Recovered/Resolved - )	withdrawn - [304d - 1{DF} - Intramuscular use])	
EU-EC- 10013520579	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myasthenia gravis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013520613	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Optic neuritis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013522071	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Unknown - ), Erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Unknown - ),  Herpes zoster (n/a - Recovering/Resolving	۱۱٫۵۱٫	
										- ), Pain (n/a - Unknown - ),		
										Pruritus (n/a - Unknown - ),		
										Rash (n/a - Unknown - )		
EU-EC- 10013522531	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Headache (n/a - Recovered/Resolved - ),	applicable - [1d - n/a - Intramuscular use])	
										Impaired work ability (n/a - Unknown - ),		
										Mobility decreased (n/a - Recovered/Resolved -),		
										Pain (n/a - Unknown		
EU-EC- 10013522636	15/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013522659	15/09/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Insomnia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported
			Professional							Muscle twitching (5d - Recovered/Resolved	n/a - n/a - [n/a - n/a - n/a])	
										Vaccination site		

						·	LING LIS	ing ite	port			
										erythema (2d - Recovered/Resolved - )		
EU-EC- 10013522699	15/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013522781	15/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Joint swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013522822	15/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose fluctuation (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	INSULIN LISPRO SANOFI [INSULIN LISPRO] (C - n/: n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/
EU-EC- 10013522824	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - ), Nausea (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	n/a - [n/a - n/a - Oral use Not reported
EU-EC- 10013523192	15/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown - ) Asthenia (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013504223	14/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved - ) Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported
EU-EC- 10013504646	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immunodeficiency (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013505320		Spontaneous	Healthcare Professional	Area	Not available	Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving Other Medically Important Condition), Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving Other Medically Important Condition), Muscle spasms (n/a - Recovering/Resolving Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013505363	14/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] - Insomnia - n/a - [n/a - n n/a]),  SENNA [SENNOSIDE A+B] [SENNOSIDE A+B] (C - Constipation - n/a - [n/a - n/a]),  [SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - Depression - n/a - [n/a - n n/a])

										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
:U-EC- 0013505420	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Palpitations (1d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC- 10013506251	14/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dengue virus test positive (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
TH 50	14/00/2022	Carabanan	New	5	Not an effective	12.17	Net	Famala	No	Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		Not were to d
EU-EC- 10013506859	14/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (14d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013507526	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),  Vaginal haemorrhage (n/a - Recovering/Resolving - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-	14/00/2022	Carabanana	Nac	F	Not an allele	12.17	Adolescent	Mala	N-	Vision blurred (1d - Recovered/Resolved - Other Medically Important Condition)	COMIDNATY	Not reported
10013507833	14/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Alopecia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013508604	14/09/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013508674	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013508775	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (21d - Recovered/Resolved - ), Dysmenorrhoea (n/a - Recovered/Resolved - ), Heavy menstrual bleeding (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
										Immunisation reaction (1d - Recovered/Resolved - )		
EU-EC- 10013508828	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menarche (n/a - Recovered/Resolved - ), Menstruation irregular (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013508840	14/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013510151	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Formanek, A Myocarditis following mRNA vaccine. Wien Med Wochenschr. 2022;10.1007/s10354-022-00959-6. doi:10.1007/s10354-022-00959-6	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Other Medically Important Condition)		
J-EC- 0013511115	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Fall (n/a - Unknown - Other Medically Important Condition),		
										Fatigue (1d - Recovered/Resolved - Other Medically Important Condition),		
										Limb discomfort (1d - Recovered/Resolved - Other Medically		
										Important Condition), Nausea (1d - Recovered/Resolved		
										- Other Medically Important Condition),		
										Pain (1d - Recovered/Resolved - Other Medically Important Condition),		
										Peripheral coldness (1d - Recovered/Resolved - Other Medically Important Condition),		
										Tinnitus (0d - Recovered/Resolved - Other Medically Important Condition),		
										Tremor (1d - Recovered/Resolved - Other Medically Important Condition),		
	/					10.17				Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)		
-EC- 013511127	14/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	""	
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),		
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)		
-EC- 013511178	14/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),	- n/a])	
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),		
										Myalgia (n/a - Unknown - Other Medically Important Condition),		
										Tremor (n/a -		

										Medically Important Condition)		
EU-EC- 10013511975	14/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Systemic lupus erythematosus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC- 10013512202	14/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										(n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013512494	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (368d - Recovered/Resolved - ), Nausea (368d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Pain in extremity (368d - Recovered/Resolved - ), Pyrexia (3d -		
	14/09/2022	Spontaneous		European	Not available		Adolescent	Female	No	Recovered/Resolved - ) Headache (n/a -	COMIRNATY	Not reported
10013512518			Professional	Economic Area		Years				Unknown - ),  Pyrexia (n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	
EU-EC- 10013512548	14/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	(Ma - Onklown - ) Abdominal pain upper (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[IBUPROFEN] (C - Malaiss Unknown - [n/a - n/a - n/
										Pyrexia (3d - Recovered/Resolved - )		
EU-EC- 10013512561	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hyperprolactinaemia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Menstruation irregular (n/a - Unknown - ), Urticaria (3d - Recovered/Resolved - Other Medically		
EU-EC- 10013491544	13/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Presyncope (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013491572	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (30d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013492196	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - n/a - n/a]	Not reported
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	, <b>, ,</b>	
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-	12/00/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Malo	No	Herpes zoster (n/a -	COMIRNATY	Not reported

										Hospitalisation),	n/a - n/a - [1d - n/a - Intramuscular use])	
										Post herpetic neuralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
J-EC- 0013493656	13/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
J-EC- 1013494484	13/09/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),		
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),		
										Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition),		
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),		
										Seizure (0d - Recovered/Resolved - Other Medically Important Condition),		
										Syncope (n/a - Unknown - Other Medically Important Condition),		
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- .0013494522	13/09/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Heart rate increased (n/a - Unknown - Other Medically Important Condition),		
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),		
										Hypoacusis (n/a - Unknown - Other Medically Important Condition),		
										Nausea (n/a - Unknown - Other Medically Important Condition),		
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)		
U-EC- 0013495718	13/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
		-								Mobility decreased (n/a - Unknown - )		
EU-EC- 10013496474	13/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- .0013496543	13/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown - ), Menstruation delayed (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported

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EU-EC- 10013497246	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Condition) COVID-19 (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported
				Area						Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically	immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC- 10013497249	13/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition),	COVID-19 immunisation - Not	INTUNIV [GUANFACINE] n/a - n/a - [n/a - n/a - n/ [CALCIUM, MAGNESIUM]
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])	n/a - n/a - [n/a - n/a - n/ [METHYLPHENIDATE HYDROCHLORIDE] (C - n n/a - [n/a - n/a - n/a])
EU-EC- 10013498984	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013501463	13/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Odynophagia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	COVID-19 MRNA VACCIN MODERNA (CX-024414) [COVID-19 MRNA VACCII MODERNA (CX-024414)] COVID-19 immunisation applicable - [1d - 1{DF} - n/a])
		-								Vaccination site pain (n/a - Unknown - )		
EU-EC- 10013482722	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013482737	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Fatigue (5d - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - Intramuscular use])	
										Headache (2d - Recovered/Resolved - )		
EU-EC- 10013482989		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Oligomenorrhoea (n/a - Recovered/Resolved - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CYANOCOBALAMIN] (C - - n/a - )
EU-EC- 10013483002	12/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Arthralgia (1d - Recovered/Resolved - ), Fatigue (1d -	1{DF} - Intramuscular use])	
										Recovered/Resolved - ),  Myalgia (1d - Recovered/Resolved		
EU-EC- 10013483508	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular use])	
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically		
EU-EC-	12/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Important Condition) Depression (n/a -	TOZINAMERAN	Not reported

10013484565		Healthcare Professional	European Economic Area		Years	Specified			Unknown - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	
									Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune (n/a - Unknown - Caused/Prolonged Hospitalisation), Laziness (n/a - Unknown -	applicable - [1d - n/a - n/a])	
									Caused/Prolonged Hospitalisation), Spleen disorder (n/a - Unknown - Caused/Prolonged		
EU-EC- 12/09/ 12/09/	2022 Spontaneo		Non European Economic Area	Cole, L Multisystem Inflammatory Syndrome after Breakthrough SARS- CoV-2 Infection in 2 Immunized Adolescents, United States, Emerging Infectious Diseases, 2022;28(7):1456- 1459. doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Female	No	Hospitalisation)  Multisystem inflammatory syndrome (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013485347	2022 Spontaneo		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
									Hospitalisation),  Pustule (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Pyrexia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Rash (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Rash maculo-papular (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Rash vesicular (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Stevens-Johnson syndrome (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
									Urticaria (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Vaccination site erythema (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),		
									Vaccination site swelling (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)		
U-EC- 0013486795	2022 Spontaneo	us Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Dysgeusia (n/a -	- n/a])	[CODEINE PHOSPHAT PARACETAMOL DC, C PHOSPHATE, PARACE DC 96 %, PARACETA! CODEINE PHOSPHATI n/a - n/a - [n/a - n/a [DESOGESTREL] (C -
									Important Condition),		n/a - [n/a - n/a - n/a]) [FLUOXETINE, FLUOXI

										(n/a - Not Recovered/Not Resolved - )		
U-EC- 0013486853	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (n/a - Not Recovered/Not Resolved - ), Peripheral coldness (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
U-EC- 0013486867	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Allodynia (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	IBUPROFEN [IBUPROFEN IBUPROFEN SODIUM] (Cn/a - n/a - [n/a - 400mg n/a]),
										Amnesia (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])	[AMITRIPTYLINE HYDROCHLORIDE] (C - Neuralgia - n/a - [314d - 50mg - n/a])
										Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Blindness (n/a - Unknown - Other Medically Important Condition),		
										Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Conversion disorder (n/a - Unknown - Other Medically Important Condition),		
										Deafness unilateral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Dysphagia (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Ear haemorrhage (n/a - Unknown - Other Medically Important Condition),		
										Ear pain (n/a - Unknown - Other Medically Important Condition),		
										Erythema (n/a - Unknown - Other Medically Important Condition),		
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Feeling abnormal (n/a - Unknown - Other Medically Important Condition),		
										Gastrointestinal disorder (n/a - Unknown - Other Medically Important Condition),		
										Headache (n/a - Unknown - Other Medically Important Condition),		
										Hyperaesthesia (n/a - Unknown - Other Medically Important Condition),		
										Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition),		
										Memory impairment (n/a - Not Recovered/Not Resolved - Other		

EU-EC- 10013486972		Spontaneous	Healthcare Professional		Not available  Not available	12-17 Years	Adolescent		No	Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Otorrhoea (n/a - Unknown - Other Medically Important Condition), Otorrhoea (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Resolved - Other Medically Important Condition), Pain of skin (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition), Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC- 10013487011		Spontaneous	Non Healthcare	Non European Economic Area  Non European European European European	Not available  Not available	12-17 Years	Specified		No	Axillary mass (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Lymphadenitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Lymphoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Lymphoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Mass (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Pectus excavatum (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Skin disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Tenderness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Tenderness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Tenderness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)  COVID-19 (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)  COVID-19 (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)  COVID-19 (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])  COMIRNATY [TOZINAMERAN] (S -	Not reported  Not reported
	12/02/2022	Coorter	Professional	Economic Area	Net and able			For-J	Na	- Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not your
EU-EC- 10013488002	12/09/2022	Spontaneous	Non Healthcare	European Economic	Not available		Not Specified	Female	No	Dizziness (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported

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			Professional	Area						Vomiting (0d - Recovered/Resolved - )	n/a - n/a - [n/a - n/a  - n/a])	
EU-EC- 10013488339	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] - Cerebrovascular acciden n/a - [n/a - n/a - n/a]),
										Arthralgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),	- n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE - Depression - n/a - [n/a - - n/a]),
										Dyspnoea (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		[NORETHISTERONE ACETATE] (C - Contracept - n/a - [n/a - n/a - n/a])
										Headache (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
										Hyperaesthesia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
										Lymphadenopathy (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		
										Myalgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		
										Pericarditis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		
										Pyrexia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
										Vaccination site pain (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)		
EU-EC- 10013488370	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash erythematous (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013488734	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blister (n/a - Unknown - ), Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013488858	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (3d - Recovered/Resolved - ), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013489734	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Cole, L Multisystem Inflammatory Syndrome after Breakthrough SARS- CoV-2 Infection in 2 Immunized Adolescents, United States. Emerging Infectious Diseases. 2022;28(7):1456- 1459. doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Male	No	(n/a - Unknown - ) Multisystem inflammatory syndrome (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013476397	11/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Recovered/Resolved - ), Fatigue (n/a -	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a])
										Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )		
EU-EC- 10013463514	09/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013465077	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Unknown - ),  Confusional state (1h - Unknown - ),  Delusion (1h - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous use])	Not reported

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										Heart rate abnormal (1h - Not Recovered/Not Resolved - ),		
										Hyperhidrosis (1h - Unknown - )		
EU-EC- 10013465113	09/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (1mo - Unknown - ), Lymphadenopathy (1mo - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013466744	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Crohn's disease (91d Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-	00/00/2022	Cooptonoous	Non	European	Net agilable	12.17	Not	Fomalo	No	Nausea (91d - Recovered/Resolved With Sequelae - )	COMIDNATY	Not reported
10013466848	09/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013467039	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (388d - Recovered/Resolved With Sequelae - ), Vasculitis (388d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013467265	09/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	With Sequelae - ) Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL, FERR FUMARATE] (C - Menstrus irregular - n/a - [n/a - n/a n/a])
										Dizziness (n/a - Unknown - Other Medically Important Condition),	7,20	
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Pain in extremity (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013468660	09/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	Not reported
										(n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not	1{DF} - Intramuscular use])	
										Recovered/Not Resolved - ), Pyrexia (n/a - Not		
										Recovered/Not Resolved - ), Sleep disorder (n/a - Not Recovered/Not		
										Resolved - ),  Visual impairment (n/a - Not Recovered/Not		
EU-EC-	09/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Resolved - )	COMIRNATY	Not reported
10013469654			Healthcare Professional	Economic Area		Years	Specified			- Not Recovered/Not Resolved - ), Headache (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10013470817	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Moncada-madrazo, M To keep in scope: vulvar aphthous ulcers after COVID-19 vaccination. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):235. doi:10.1016/j.jpag.2022.01.112	12-17 Years	Not Specified	Female	No	Aphthous ulcer (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
					Moncada-madrazo, M "Supplementary data" To keep in scope: vulvar aphthous ulcers after COVID-19 vaccination. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):235. doi:10.1016/j.jpag.2022.01.112						. , -1/	
EU-EC- 10013471039	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Wilson, H Late Gadolinium Enhancement after COVID-19 Vaccination. Radiol Cardiothorac Imaging. 2021;3(5):10.1148/ryct.2021210199. doi:10.1148/ryct.2021210199	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013471066	09/09/2022	Spontaneous	Non Healthcare	Non European	Not available		Not Specified	Female	No	Pain (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S -	Not reported

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			Professional	Economic Area						Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (n/a - Not	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
EU-EC-	09/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Recovered/Not Resolved - Other Medically Important Condition) Rash pruritic (n/a -	COMIRNATY	Not reported
10013471278			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving - ), Urticaria (n/a - Recovering/Resolving - ), Vaccination site rash (n/a - Recovering/Resolving	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10013471400	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ) Asthenia (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Myocardial necrosis marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
										Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Life Threatening)		
EU-EC- 10013472154	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013453907	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Joint effusion (n/a - Recovered/Resolved - ), Lymphadenopathy (29d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC- 10013454490	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Infection susceptibility increased (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC- 10013454491	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Migraine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC- 10013454720	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013455178	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Nerve stimulation test abnormal (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013455772	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (3wk - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013455977	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

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										Lymphadenopathy (n/a - Recovered/Resolved - ), Pyrexia (n/a -		
										Recovered/Resolved - ),  Vomiting (1d -		
EU-EC-	08/09/2022	Spontaneous		European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved - ) Abdominal pain (n/a	COMIRNATY	Not reported
10013456226			Professional	Economic Area		Years				- Not Recovered/Not Resolved - ), Cough (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	
										Hypotonia (n/a - Not Recovered/Not Resolved - ),		
										Vomiting (n/a - Not Recovered/Not Resolved - ),		
										Weight bearing difficulty (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013456696	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Heavy menstrual bleeding (n/a - Recovered/Resolved - ),	immunisation - n/a - [n/a - n/a - n/a])	
										Petechiae (n/a - Recovered/Resolved - ),		
										Pruritus (n/a - Recovered/Resolved - ),		
										Rash (n/a - Recovered/Resolved - )		
EU-EC- 10013457487	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported
										Sudden hearing loss (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	
										Tinnitus (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013458429	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - 1{DF} - Intramuscular use])	
EU-EC- 10013458525	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	[VALPROIC ACID, SODIUN VALPROATE] (C - Epilepsy n/a - [n/a - n/a - n/a])
EU-EC- 10013458551	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported
EU-EC- 10013458682	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported
EU-EC- 10013458976	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T Severe Rhabdomyolysis Temporally Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149(1):272	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Unknown - Life Threatening, Other Medically Important Condition)	Intramuscular use]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
EU-EC- 10013459005	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T Severe Rhabdomyolysis Temporally Associated with sars-cov-2 Vaccine in an Adolescent, Pediatrics, 2022;149(1):272	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Other Medically Important Condition),	n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Rhabdomyolysis (n/a - Unknown - Life Threatening, Other Medically Important Condition)	n/a - n/a])	
EU-EC- 10013459015	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T Severe Rhabdomyolysis Temporally Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149 (1):272	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Other Medically Important Condition)		
:U-EC- 0013459749	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Ma <b>j</b> e	No	Important Condition) Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Irritability (n/a - Recovering/Resolving - ),		
										Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not		
										Recovered/Not Resolved - ), Pain (n/a - Not		
										Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not		
										Resolved - ),  Vaccination site pain (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013460568	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving - ), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013460592	08/09/2022	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - ) Autonomic neuropathy (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported
.0010 100032			n oresistical	Economic Area		lears	oped.ii.ed			Recovering/Resolving - Other Medically Important Condition),		
										Encephalitis autoimmune (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Exophthalmos (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013460648		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013460652	08/09/2022	Spontaneous	Professional		Baird, T Severe Rhabdomyolysis Temporally Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149 (1):272	12-17 Years	Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Overdose (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Unknown - Other Medically Important Condition),  Product preparation	11/a - 11/a] <i>)</i>	
										error (n/a - Unknown - Other Medically Important Condition),		
										Rhabdomyolysis (n/a - Unknown - Life Threatening, Other Medically Important Condition)		
EU-EC- 10013461186	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T Severe Rhabdomyolysis Temporally Associated with sars-cov-2 Vaccine in an Adolescent, Pediatrics, 2022;149(1):272	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
										Rhabdomyolysis (n/a - Unknown - Other Medically Important Condition)	n/a - n/a])	
EU-EC- 10013461660	U8/U9/2022 	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC- 10013444423	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved - ), Dysmenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular	Not reported
										Recovered/Resolved - ),  Dyspnoea (11d - Recovered/Resolved With Sequelae - )	use])	
										With Sequelae - ), Pyrexia (3d - Recovered/Resolved - )		
EU-EC- 10013444466	07/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Back pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported

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				Area						- ), Injection site pain (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Somnolence (3d - Recovered/Resolved	COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	
	EU-EC- 10013447724	07/09/2022	Spontaneous	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Administration site pain (n/a - Recovered/Resolved - ), Body temperature increased (2d - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
	EU-EC- 10013448292	07/09/2022	Spontaneous	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- )  Body temperature increased (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
	EU-EC- 10013448717	07/09/2022	Spontaneous	Economic	Not available		Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - ), Chills (n/a - Recovering/Resolving - ), Fall (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Muscular weakness (n/a - Recovering/Resolving - ), Vision blurred (n/a - Recovering/Resolving - ), Visual impairment (n/a - Recovering/Resolving - ), Visual impairment (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LYMECYCLINE, TETRACYCLINE] (C - n/a - Unknown - [n/a - n/a - n/:
	EU-EC- 10013448718	07/09/2022	Spontaneous	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (230d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (230d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{OF} - Intramuscular use])	[ALLERGEN EXTRACT, ALLERGENS, POLLEN & PLANT EXTRACT, ALNUS GLUTINOSA L., AMBROSIA ARTEMISIIFOLIA, ANTHOXANTHUM ODORA' L., AATEMISIA VULGARIS AVENA FATUA WHOLE, BROMUS INERMIS WHOLE DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., ANTHOXANTHUM ODORA' L., LOLIUM PERENNE L., PRATENSIS L., HOLCUS LANATUS, FESTUCA PRATENSIS L., HOLCUS LANATUS, FESTUCA PRATENSIS CAPILLARIS L., CYNODON DACTYLON (L.) PERS,, ARRHENATHERUM ELATIUS, AVENA SATIVA L TRITICUM AESTIVUM, DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., ANTHOXANTHUM ODORA' L., LOLIUM PERENNE L., PRATENSIS L., ZEA MAYS HORDEUM VULGARE L., AVENA SATIVA L., TRITICI AESTIVUM, ZEA MAYS L., HORDEUM VULGARE L., EFULA, BETULA PENDUL ROTH, BETULA PENDUL ROTH, BETULA PENDUL EXTRACT, CORYLUS AVELLA L., CARPINUS GLUTINO POLLEN EXTRACT, SETULU CORYLUS AVELLANA L., ALNUS GLUTINOSA L., BETULUS L., CAT EPITHEL CORYLUS AVELLANA L., CATULUS AVELLANA L., CORYLUS AVELLANA L., COR

										L., DACTYLIS GLOMERATA PHLEUM PRATENSE L., ANTHOXANTHUM ODORA' L., LOLIUM PERENNE L., PRATENSIS L., DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., LOLIUM PERENNE L., DERMATOPHAGOIDES FARINAE, DERMATOPHAGOIDES FARINAE, DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES PARINAE, DOG EPITHELIA FRAXINUS EXCELSIOR L., HAZEL POLLEN ALLERGOI FORMALDEHYDE MODIFIE BIRCH POLLEN ALLERGOI FORMALDEHYDE MODIFIED JUNIPERUS ASHEI BUCHHOLZ, LOLIU PERENNE L., OLEA EUROFL, PARIETARIA JUDAICA I PARIETARIA OFFICINALS PHLEUM PRATENSIS L., SECALE CEREALE L.] (C - Immune enhancement therapy - n/ [n/a - 4[drp] - Sublingual use])
EU-EC- 10013448783	07/09/2022	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Chest pain (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013448849	07/09/2022	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Asthenia (n/a - Not Recovered/Not Resolved - ),  Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),  Blood alkaline phosphatase decreased (n/a - Unknown - ),  Blood copper decreased (n/a - Unknown - ),  Blood copper decreased (n/a - Unknown - ),  Blood creatinine decreased (n/a - Unknown - ),  Blood treatinine decreased (n/a - Unknown - ),  CSF glucose increased (n/a - Unknown - ),  CSF glucose increased (n/a - Unknown - Other Medically Important Condition),  CSF protein decreased (n/a - Unknown - ),  Dyskinesia (n/a - Unknown - ),  Dyspnoea (n/a - Unknown - ),  Gastritis (n/a - Unknown - ),  Headache (n/a - Recovered/Resolved - ),  Mean cell haemoglobin concentration increased (n/a - Unknown - ),  Myocarditis (n/a - Unknown - ),  Respiratory disorder (n/a - Unknown - ),  Respiratory disorder (n/a - Unknown - ),  Salivary hypersecretion (n/a - Not Recovered/Not	AZATHOPRINE [CAZHHOPRINE] (S - n/a - Unknown - [n/a - 100mg - n/a]),  IVABRADINE HYDROCHLORIDE [IVABRADINE HYDROCHLORIDE] (S - n/a - Unknown - [n/a - 10mg - n/a]),  PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE, PANTO	Not reported

										Resolved -		
	07/09/2022	Spontaneous		Non	Not available	12-17	Not	Male	No	Caused/Prolonged Hospitalisation) Chest pain (4d -	COMIRNATY	Not reported
0013449639			Professional	European Economic Area		Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (65h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	
										Myopericarditis (65h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Recovered/Resolved		
U-EC- 0013450050	07/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Genital haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
U-EC- 0013450142	07/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
U-EC- 0013450147	07/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Sinus tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
U-EC- 0013450161	07/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported
U-EC- 0013450219	07/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{OF} - Intramuscular use])	Not reported
U-EC- 0013450232	07/09/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition)  Amenorrhoea (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported
EU-EC- 0013450235	07/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Intramuscular use])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013450680	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition)  Death (n/a - Fatal - Results in Death, Other Medically Important Condition),  Immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition),  Off label use (n/a - Fatal - Results in Death, Other Medically Important Condition), Tatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013450725	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Nishibayashi, H Myocarditis in 13- Year-Old Monochorionic Diamniotic Twins After COVID-19 Vaccination. Journal of Clinical Immunology. 2022;115th:10,1007/s10875-022- 01360-z. doi:10.1007/s10875-022-	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST	COVID-19 immunisation - Not applicable - [1d - n/a	Not reported

0.11.2022	15.17					Run	Line Lis	ung Re	port			
					01360-z Nishibayashi, H Monochorionic-diamniotic twin sibling cases of myocarditis that developed after COVID-19 vaccination. The 115th Oita Regional Meeting of Japan Pediatric Society, 2022;3, doi:10.1007/s10875-022-01360					segment elevation (n/a - (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
EU-EC- 10013450985	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Sick relative (n/a - Unknown - ) Confusional state (n/a - Recovered/Resolved - ), Eye movement disorder (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [INFLUENZA A VIRUS A/BRISBANE/10/2010	
										- ), Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved	(H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (5 - n/a - Not applicable - [n/a - n/a - Intramuscular use])	
EU-EC-	07/09/2022	Spontaneous		European	Not available	12-17	Adolescent	Female	No	- ) Malaise (n/a -	COMIRNATY	Not reported
10013452696			Professional	Area		Years				Unknown - ), Nausea (n/a - Unknown - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	
EU-EC-	07/00/2022	Caratana	11	F	Not available	12-17	A d - 1	F	NI-	Vaccination site pain (n/a - Unknown - )	COMIDNIATY	Not on out of
10013452702	07/09/2022	Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent	remale	No	Abdominal pain (n/a - Unknown - ), Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013452764	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013433881	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Maternal exposure timing unspecified (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013433968	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013434841	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sutcu, M Rhabdomyolysis after BNT162b2 mRNA Covid-19 vaccine in an adolescent male. Malawi Medical Journal. 2022;34(2):154-156. doi:10.4314/mmj,v34i2.13	12-17 Years	Not Specified	Male	No	Unknown - ) Rhabdomyolysis (n/a Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013435075	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	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
EU-EC- 10013435584	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Extensive swelling of vaccinated limb (4d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ), Injection site reaction (4d - Recovered/Resolved - ), Lymphadenopathy (4d - Recovered/Resolved - ), Oral pruritus (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
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										Pyrexia (4d - Recovered/Resolved - ),		
										Skin disorder (4d - Recovered/Resolved - )		
EU-EC- 10013435778	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1min - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013435853	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site erythema (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Orthostatic hypotension (1min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013435869	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tinnitus (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
10013436797	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (236d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (236d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013436981	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC- 10013437410	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blindness (1d - Recovered/Resolved - Other Medically Important Condition), Deafness (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PIZOTIFEN, PIZOTIFEN MALATE] (C - Migraine - r [n/a - n/a - n/a])
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d -		
										Recovered/Resolved - Other Medically Important Condition)		
EU-EC- 10013438489	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013438592	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013438640	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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										Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013438661	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown - ), Syncope (0d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013439149	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oligomenorrhoea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{OF} - Intramuscular use])	Not reported
										Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013439299	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013439430	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Oligomenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013439485	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - )  Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC- 10013439846	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved - Other Medically Important Condition), Limb discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Pain (1d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC- 10013440298	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (0d - Recovered/Resolved - ), Hypotension (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Malaise (0d - Recovered/Resolved - ), Vertigo (0d - Recovered/Resolved		
EU-EC- 10013440361	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (20min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013440421	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (20min - Recovered/Resolved - ), Hypotension (20min - Recovered/Resolved - ), Malaise (20min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Recovered/Resolved - ), Presyncope (20min - Recovered/Resolved - ), Vertigo (20min - Recovered/Resolved		
EU-EC- 10013440884	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Nishibayashi, H Monochorionic- diamniotic twin sibling cases of myocarditis that developed after COVID-19 vaccination. The 115th Oita	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

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					Regional Meeting of Japan Pediatric Society. 2022;115th:3 Nishibayashi, H Myocarditis in 13-Year-Old Monochorionic Diamniotic Twins After COVID-19 Vaccination. Journal of Clinical Immunology.					- Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a -	applicable - [n/a - n/a - n/a])	
					2022;10.1007/s10875-022-01360-z. doi:10.1007/s10875-022-01360-z					Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
										Electrocardiogram ST segment elevation (n/a -		
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),		
EU EC	06 100 12022	Caratana	New	N	Nat a relation	12.17	Net	F1-	NI-	Sick relative (n/a - Unknown - )	TOZINIAMEDANI	[DADACETAMOLILIC
EU-EC- 10013440905	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Dysmenorrhoea - n/a - [n, n/a - n/a])
										Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- 11/4])	
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013440915	06/09/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Feeling abnormal (n/a - Unknown - ), Limb discomfort (n/a		
										- Unknown - Other Medically Important Condition),		
										Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition),		
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013440965	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Blood folate - n/a - [n/a - n/a - n/a])
										Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),		
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),		
										Influenza like illness (3d - Recovered/Resolved		
										- Other Medically Important		
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										Pain (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013442376	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013442514	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Martinez-cabriales, S Comment on " Toxic epidermal necrolysis (TEN) after first dose of Pfizer (BNT16Zb2) vaccination and pharmacogenomic-based-point-care support: First case report in pediatric and review of literature" Pediatric Dermatology. 2022;39(4):671-672. doi:10.1111/pde.14987 Siripipattanamongkol, N Toxic epidermal necrolysis after first dose of Pfizer-BioNTech (BNT16Zb2) vaccination with pharmacogenomic testing. Pediatric Dermatology. 2022;39(4):601-605. doi:10.1111/pde.15074	12-17 Years	Not Specified	Female	No	Toxic epidermal necrolysis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013442545	06/09/2022	Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN] (S - [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013442783	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Neurological examination normal (n/a - Not Recovered/Not Resolved - ), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SERTRALINE, SERTRALII HYDROCHLORIDE] (C - n n/a - [n/a - n/a - n/a])
EU-EC- 10013442786	06/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013443189	06/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Nodule (n/a - Recovering/Resolving - ), Pyrexia (n/a - Unknown - )	COMIRNATY	Not reported
EU-EC- 10013443214	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Depressed mood (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Rhinorrhoea (n/a - Recovering/Resolving Resolving/Resolvi	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC- 10013423883	05/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- )  Dysmenorrhoea (n/a Not Recovered/Not Resolved - Other Medically Important Condition),  Muscle spasms (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013423928	05/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving - Other Medically Important Condition),  Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),  Headache (n/a - Recovered/Resolved - Other Medically Important Condition),  Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),  Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),  Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL] (C - n/a n/a - [n/a - n/a - n/a])

							Line Lis			Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)		
U-EC- 0013424761	05/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
U-EC- 0013425320	05/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
U-EC- 0013426544	05/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
J-EC- 0013426861	05/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported
										Hypotension (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),		
										Palpitations (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),		
										Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
U-EC- 0013429147	05/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{OF} - Intramuscular use])	Not reported
										Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not		
										Recovered/Not Resolved - Other Medically Important Condition)		
U-EC- 0013429214	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Testicular torsion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported
U-EC- 0013429502	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intravenous use])	Not reported
										Decreased appetite (n/a - Not Recovered/Not Resolved - ),		

December   Processes   Proce		10.17	ı	ı	ı	I	ı	LING EIS	ı ııgırıc	,port	Handasha (n/a Not	I	ı
Married   Marr											Headache (n/a - Not Recovered/Not Resolved - )		
1995   1995	EU-EC- 10013429650	05/09/2022	Spontaneous		European Economic	Not available			Male	No	Chest pain (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
March   Marc													
Part	EU-EC- 10013429739	05/09/2022	Spontaneous	Healthcare	European Economic	Not available			Female	No	Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Nasal congestion (n/a - Unknown - Other Medically Important Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	ETHINYLESTRADIOL] (C - Hormone level abnormal - - [n/a - n/a - n/a]), [PROCHLORPERAZINE] (C Nausea - n/a - [n/a - n/a -
13-77   Mist   13-7											Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important		
13-14   13-14   13-14   14-1	EU-EC- 10013429924	05/09/2022	Spontaneous	Healthcare	Economic	Not available			Male	No	COVID-19 (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
Recovered/Resolved   -	EU-EC- 10013430811	05/09/2022	Spontaneous		European Economic	Not available			Male	No	(n/a - Recovered/Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
European   Professional   Professi											Recovered/Resolved - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved		
Spontaneous	EU-EC- 10013430871	05/09/2022	Spontaneous	Healthcare	Economic	Not available			Male	No	Taste disorder (n/a - Recovering/Resolving	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
EU-EC- 10013430890	EU-EC- 10013430874	05/09/2022	Spontaneous	Healthcare	Economic	Not available			Female	No	Recovered/Resolved - ), Fall (n/a - Unknown - ), Thirst (n/a - Unknown - ), Vaccination site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
EU-EC- 05/09/2022 Spontaneous Non European Healthcare Economic Hea	EU-EC- 10013430890	05/09/2022	Spontaneous	Healthcare	Economic	Not available			Female	No	- ) Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported
	EU-EC- 10013431037	05/09/2022	Spontaneous	Healthcare	Economic	Not available			Female	No	Pruritus (n/a -		Not reported

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										Unknown - ),	n/a - n/a - [n/a - n/a - n/a])	
										Urticaria (n/a - Not Recovered/Not		
:U-EC-	05/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Resolved - ) Diarrhoea (n/a -	COMIRNATY	Not reported
0013431090				Economic		Years	Specified			Recovering/Resolving	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	·
										Myalgia (3d -	- n/a])	
										Recovered/Resolved		
										Nausea (n/a - Recovering/Resolving		
U-EC- (	05/09/2022	Spontaneous	Healthcare	Furopean	Not available	12-17	Adolescent	Female	No	- ) Headache (n/a -	COMIRNATY	Not reported
0013432238	,,		Professional			Years				Unknown - ),	[TOZINAMERAN] (S - COVID-19	
										Malaise (n/a - Unknown - ),	immunisation - Not applicable - [1d -	
										Pyrexia (n/a -	1{DF} - n/a])	
	03/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Unknown - ) Myopericarditis (n/a -	COMIRNATY	Not reported
10013418482			Healthcare Professional			Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
U-EC- 0013418552	03/09/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C -
0013 110332			Professional			licars	Specifica			Recovered/Not Resolved - )	COVID-19 immunisation - Not	- n/a - )
										inesolved - )	applicable - [n/a - n/a - Intramuscular	
EU-EC- (	02/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	Paraesthesia (1d -	use]) TOZINAMERAN	NOVORAPID [INSULIN
0013409082	,,			European		Years	Specified			Recovered/Resolved - Other Medically		ASPART] (C - Type 1 diabe mellitus - n/a - [n/a - n/a
			, rondona.	Area						Important Condition)	immunisation - Not applicable - [1d - n/a	n/a])
:U-EC- (	02/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Adult	Male	No	SARS-CoV-2 test	- n/a]) COMIRNATY	Not reported
.0013409278	, ,		Professional			Years				positive (n/a - Unknown - ),	[TOZINAMERAN] (S - COVID-19	
										Vaccination failure	immunisation - Not applicable - [n/a -	
										(n/a - Unknown - )	1{DF} - Intramuscular use])	
EU-EC- 10013409351	02/09/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S -	Not reported
			Professional	Economic Area						Recovered/Not Resolved -	COVID-19 immunisation - Not	
										Disabling),	applicable - [1d - n/a - n/a])	
										Ageusia (n/a - Not Recovered/Not Resolved - Disabling),		
										Catatonia (n/a - Not		
										Recovered/Not Resolved - Disabling),		
										Central nervous		
										system inflammation (n/a - Not		
										Recovered/Not Resolved - Disabling,		
										Other Medically Important Condition),		
										Confusional state		
										(n/a - Not Recovered/Not		
										Resolved - Disabling),		
										Fatigue (n/a - Not		
										Recovered/Not Resolved -		
										Disabling),		
										Malaise (n/a - Not Recovered/Not Resolved -		
										Disabling),		
										Musculoskeletal disorder (n/a - Not		
										Recovered/Not Resolved -		
										Disabling),		
										Nausea (n/a - Not Recovered/Not		
										Nausea (n/a - Not		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Seizure (n/a - Not Resolved - Disabling),		
										Nausea (n/a - Not Recovered/Not Resolved – Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved – Disabling), Pyrexia (n/a - Not Recovered/Not Resolved – Disabling), Seizure (n/a - Not Recovered/Not Recovered/Not Resolved – Disabling,		
										Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Seizure (n/a - Not Recovered/Not Resolved - Disabling), Seizure (n/a - Not Recovered/Not Resolved - Disabling),		

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										Selective mutism (n/a - Not Recovered/Not Resolved - Disabling),  Syncope (n/a - Not Recovered/Not Resolved - Disabling, Other Medically		
										Important Condition),  Tic (n/a - Not Recovered/Not Resolved - Disabling),		
										Tourette's disorder (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
EU-EC- 10013409579	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	SARS-CoV-2 test positive (n/a - Unknown - ),  Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013409580	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown - ), Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported
EU-EC- 10013409654	02/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
										Vomiting (2d - Recovered/Resolved		
EU-EC- 10013409773	02/09/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown - ), Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013410023	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013410292	02/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown - ), Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013411043	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013411141	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
										Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Decreased appetite (n/a - Unknown - Other Medically Important Condition),		
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Feeling hot (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a -		
										Recovering/Resolving - Other Medically Important Condition), Inappropriate		
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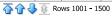
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										schedule of product administration (n/a - Unknown - ),		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Piloerection (n/a - Unknown - Other Medically Important Condition),		
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),		
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC- 10013411209	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Breast neoplasm (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC- 10013414196	02/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Unknown - ), Menstruation delayed (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} -	Not reported
EU-EC- 10013414282	02/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Inflammation (n/a - Not Recovered/Not Resolved - )	Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013414739	02/09/2022	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Female	No	Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE PHOSPHATE HEMIHYDRATE PHEUR, IBUPROFEN PH. EUR, IBUPROFEN PH. EUR, CODEINE PHOSPHATE PH, EUR, CODEINE PHOSPHATE, IBUPROFEN, CODEINE PHOSPHATE, IBUPROFEN, CODEINE PHOSPHATE HEMIHYDRAI (C - Temporomandibular just syndrome - n/a - [n/a - n/n/a]),  [DIAZEPAM] (C - Temporomandibular just syndrome - n/a - [n/a - n/n/a]),  [DICLOFENAC, DICLOFEN, POTASSIUM, DICLOFEN, PORMOTER, PORMOTER, FORMOTER, PORMOTER, PHUMRARTE DIHYDRATE, PHUMRARTE DIHYDRATE PHEUR,] (C - n/a - n/a - n/a - n/a - [n/a - n/n]),  [PARACETAMOL, CODEINE PHOSPHATE] (C - Temporomandibular joint syndrome - n/a - [n/a - n/n]),  [SAI BILTAMOL, SUIL FATE I (
EU-EC- 10013414761	02/09/2022	Spontaneous		Non European	Patel, S Ouch!My Chest. Pfizer- biontech COVID-19 Vaccination		Not Specified	Male	No	Headache (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S -	[SALBUTAMOL SULFATE] ( n/a - n/a - [n/a - n/a - n/a Not reported
				Economic Area	Induced Acute Myopericarditis: A Case Report, Pediatrics, 2022;149 (1):830					Hypoaesthesia (n/a - Unknown - ), Myalgia (n/a - Unknown - ),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
										Myopericarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Paraesthesia (n/a - Unknown - ), Scar (n/a - Unknown - ),		
										Vomiting (n/a - Unknown - )		
EU-EC- 10013415138	02/09/2022	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Asthma (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported

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										Caused/Prolonged Hospitalisation, Other Medically		
EU-EC- 10013415331	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Suspected COVID-19 (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	[DESOGESTREL] (C - Premenstrual syndrome - - [n/a - n/a - n/a])
										Vulval disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10013415479	02/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual discomfort (119d - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported
										Menstruation irregular (119d - Not Recovered/Not Resolved - )	[n/a - n/a - n/a])	
EU-EC- 10013415609	02/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast engorgement (2d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Chest pain (2d - Not Recovered/Not Resolved - ),	[[iva iva iva]]	
FILEC.	02/00/2022	Carataga	Non	F	National delication	12.17	Adelessan	FI-	N-	Skin swelling (2d - Not Recovered/Not Resolved - )	COMIDNATY	Not are safed
EU-EC- 10013415639	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (234d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
										Disturbance in attention (n/a - Unknown - ),		
										Dizziness (234d - Not Recovered/Not Resolved - ),		
										Dizziness (n/a - Unknown - ),		
										Gait disturbance (234d - Not Recovered/Not Resolved - ),		
										Gait disturbance (n/a - Unknown - ),		
										Headache (234d - Not Recovered/Not Resolved - ),		
										Headache (n/a - Unknown - ),		
										Hypoaesthesia (234d - Not Recovered/Not Resolved - ),		
										Hypoaesthesia (n/a - Unknown - ),		
										Musculoskeletal discomfort (234d - Not Recovered/Not Resolved - ),		
										Musculoskeletal discomfort (n/a - Unknown - ),		
										Myalgia (234d - Not Recovered/Not Resolved - ),		
										Myalgia (n/a - Unknown - ),		
										Nausea (234d - Not Recovered/Not Resolved - ),		
										Nausea (n/a - Unknown - ),		
										Paraesthesia (n/a - Unknown - ), Tremor (234d - Not		
	02/09/2022	Spontaneous		European	Not available	12-17	Adolescent	Male	No	Recovered/Not Resolved - ) Injection site	COMIRNATY	Not reported
10013415763			Healthcare Professional	Economic Area		Years				lymphadenopathy (1d - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	
										Lymphadenopathy (1d - Not Recovered/Not Resolved - )		
EU-EC- 10013416224	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colitis ulcerative (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

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										Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - n/a])	
										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),		
										Diarrhoea haemorrhagic (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
										Flatulence (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC- 0013416350	02/09/2022	Spontaneous		Non European Economic Area	Choi, J Two adolescent cases of acute tubulointerstitial nephritis after second dose of COVID-19 mRNA vaccine. Human Vaccines & Samp; Immunotherapeutics. 2022;18(5):1-6. doi:10.1080/21645515.2022.2059308	12-17 Years	Not Specified	Male	No	Tubulointerstitial nephritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
U-EC- 0013417153	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Choi, J Two adolescent cases of acute tubulointerstitial nephritis after second dose of COVID-19 mRNA vaccine. Human Vaccines & Description of the control	12-17 Years	Not Specified	Male	No	Metabolic acidosis (n/a - Unknown - ), Sinus arrhythmia	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
					Immunotherapeutics, 2022;18 (5):1-6, doi:10.1080/21645515.2022.2059308					(n/a - Unknown - ), Tubulointerstitial nephritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	applicable - [1d - n/a - n/a])	
U-EC- 0013398182	01/09/2022	Spontaneous		Non European Economic Area	Sartor, R Association of COVID-19 Vaccination with Vulvar Ulcers in Adolescent Females. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):234. doi:10.1016/j.jpag.2022.01.110	12-17 Years	Not Specified	Female	No	Vulval ulceration (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
U-EC- .0013398825	01/09/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
:U-EC- 0013398849	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
										Chills (n/a - Unknown - Other Medically Important Condition),		
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		
										Pyrexia (n/a - Unknown - Other Medically Important Condition),		
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
U-EC- 0013399150	01/09/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	SARS-CoV-2 test positive (n/a - Unknown - ), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported
EU-EC-	01/00/2022	Spontaneous	Healthears	Furances	Not available	12 17	Not	Eemala	No	(n/a - Unknown - )	1{DF} - Intramuscular use]) COMIRNATY	Not reported
:U-EC- !0013399162	01/09/2022	apontaneous	Professional		INOL AVAIIAUIE		Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - n/a - n/a])	

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										Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - ),		
										Nausea (n/a - Not Recovered/Not Resolved - ),		
										Vomiting (n/a - Not Recovered/Not Resolved - )		
EU-EC- 10013399201	01/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013399556	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sartor, R Association of COVID-19 Vaccination with Vulvar Ulcers in Adolescent Females, Journal of Pediatric and Adolescent Gynecology. 2022;35(2):234. doi:10.1016/ji.jpag.2022.01.110	12-17 Years	Not Specified	Female	No	Vulval ulceration (n/a - Recovered/Resolved - Other Medically Important Condition)		Not reported
EU-EC- 10013400158	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Okada, M An adolescent girl diagnosed with IgA nephropathy following the first dose of the COVID- 19 vaccine. CEN Case Reports. 2022;11:376-379. doi:10.1007/s13730- 021-00679-7	12-17 Years	Not Specified	Female	No	Haematuria (n/a - Recovered/Resolved - Other Medically Important Condition), Haematuria (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
										IgA nephropathy (n/a - Unknown - Other Medically Important Condition)		
EU-EC- 10013400323	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Unknown - Other Medically Important Condition), Tremor (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC- 10013401459	01/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown - )  Cough (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC- 10013401510		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ) Chills (1d - Recovered/Resolved - ), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a n/a - [n/a - n/a - Oral use
										Unknown - ), Headache (2d - Recovered/Resolved - ),		
										Pyrexia (1d - Recovered/Resolved - ),		
										Vaccination site pain (3d - Recovered/Resolved -),		
										Vomiting (0d - Recovered/Resolved - )		
EU-EC- 10013401856	01/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	SARS-CoV-2 test positive (n/a - Unknown - ), Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported
EU-EC- 10013402271	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular use])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported
										Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	- Intramuscular use])	
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		
										Tremor (n/a - Not Recovered/Not		
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										Resolved - Caused/Prolonged Hospitalisation)		
EU-EC- 10013403414	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013403567	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Oligomenorrhoea (n/a - Not Recovered/Not Resolved - ), Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{OF} - Intramuscular use])	Not reported
EU-EC- 10013403620	01/09/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC- 10013403710	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC- 10013403806	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported



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