Line Listing Report Time run: 30/11/2022 10:07:17

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	Sorioucnocc	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011128675	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU 50	24 442 42024					10.17				Pyrexia (n/a - Not Recovered/Not Resolved -)			1000
EU-EC- 10011128739	31/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Uveitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011128859	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Paralysis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Cutaneous])	Not reported	ICSR
EU-EC- 10011129259	31/12/2021	Spontaneous	Healthcare 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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011130494	31/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Off label use (n/a - Unknown -),			
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011131359	31/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Malaise (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vaccination site erythema (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011131370	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Polymenorrhoea (n/a - Recovered/Resolved With Sequelae -			
EU-EC- 10011131383	31/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disabling) Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011131411	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Gait disturbance (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hemihypoaesthesia (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Rhinitis (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011131505	31/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

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											Important Condition),			
											Back pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
											Inflammation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
											Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
											Pyrexia (5d - Recovered/Resolved - Disabling, Other Medically Important Condition)			
	EU-EC- 10011132237	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
	EU-EC- 10011132240	31/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Rash (n/a - Recovering/Resolving -), Skin burning			
											sensation (n/a - Recovering/Resolving -),			
											Vaccination site pain (n/a - Recovering/Resolving -)			
	EU-EC- 10011132241	31/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Chest pain (0d - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Cough (0d - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Dyspnoea (0d - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10011132244	31/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Vaccination site oedema (n/a - Not Recovered/Not Resolved -),			
	EU-EC-	21/12/2021	Chantanaous	Haalthaara	Non	Not	12 17	Not	Fomale	No	Vaccination site warmth (n/a - Not Recovered/Not Resolved -)	COMIDNATY [TOZINAMEDAN]	Not reported	ICCD
	10011133929	31/12/2021	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Female	INO	diastolic decreased	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Loss of consciousness (2min			
											Recovered/Resolved - Other Medically Important Condition),			
											Nausea (n/a - Recovering/Resolving -),			
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										Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011133944	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	[FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Pulmonary embolism (n/a - Recovering/Resolving - Other Medically Important Condition)	[ETHINYLESTRADIOL, LEVONORGESTREL] (S - n/a - Unknown - [n/a - n/a - n/a])		
EU-EC- 10011133965	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Furunde (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011133982	31/12/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Female	No	Uveitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011133988	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Ma j e	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011133992	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011134326	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -), Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ATOMOXETINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]),	ICSR
										Unknown -)		[DIENOGEST, ETHINYLESTRADIOL, LACTOSE MONOHYDRATE] (C - Contraception - n/a - [n/a - n/a - n/a]),	
												[SERTRALINE] (C - Anxiety - n/a - [n/a - n/a - n/a])	
EU-EC- 10011135025	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011135180	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -), Pallor (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Unknown -), Syncope (n/a -			
										Unknown - Other Medically Important Condition)			
EU-EC- 10011135337	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011135339	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Recovered/Resolved -), Decreased appetite			
										(n/a - Recovered/Resolved -),			
										Dyspnoea (n/a - Recovered/Resolved -),			
										Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved -),			
EU-EC-	31/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Vomiting (n/a - Recovered/Resolved -) Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011135347	, , , , , , , , , , , , , , , , , , , ,		Professional		available	Years	Specified			Recovered/Not Resolved -), Headache (n/a - Not	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Not Resolved -),			

										Hypersomnia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Photosensitivity reaction (n/a - Not Recovered/Not Resolved -),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011135665	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011135757	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (15d - Recovered/Resolved - Other Medically Important Condition),		[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a -	
										Decreased appetite (15d - Recovered/Resolved - Other Medically Important Condition),		n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Headache (15d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011135847	31/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011135885	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011135961	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10011136021	31/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site discolouration (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011136101	31/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011136173	31/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved -), Immunisation reaction (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Vision blurred (2d - Recovered/Resolved			
EU-EC- 10011136177	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011136585	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (35min - Recovered/Resolved -), Syncope (35min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011136888	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- Other Medically Important Condition) COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Infection (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 100111114289		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperpyrexia (17d - Recovered/Resolved - Other Medically Important Condition)			ICSR
EU-EC- 10011114293	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										Hospitalisation),	Intramuscular])		

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										- Caused/Prolonged Hospitalisation)			
EU-EC- 100111114304	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	anaemia - n/a - [n/a - 5mg -	ICS
										, ,		[VITAMIN D] (C - Vitamin D deficiency - n/a - [n/a - 1000{DF} - Oral])	
EU-EC- 10011114338	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 10011114372	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSI
EU-EC- 10011114483	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 100111114551	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSI
										Confusional state (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Derealisation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Disorientation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Lethargy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011114556	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011114576	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apicectomy (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
										Pneumothorax (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011115028	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -), Dyspnoea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSI
										Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved			
										Hypotension (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vision blurred (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10011115100	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -), Cough (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Dizziness (n/a - Unknown -),	and an usculd [])		
										Inflammation (n/a - Unknown -),			

10011115137 Professional European Economic Area European Economic Area Specified Recovered/Resolved (S - COVID-19 immur - Caused/Prolonged Hospitalisation, Other Medically Important Condition) EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - TOZINAMERAN	n/a - Not reported ICSR
EU-EC- 10011115137 EU-EC- 10012115137 Begintance discress (n/a - Unknown -), Pyrexia (n/a - Unknown -), Respiratory distress (n/a - Unknown -) (n/a - Unknown -), Vaccination site paraesthesia (n/a - Unknown -), Wheezing (n/a - Unknown -),	n/a - Not reported ICSR
EU-EC- 10011115137 Bull-EC- 1001212021 Spontaneous Healthcare Roman Recommic Area Bull-EC- 1001212021 Spontaneous Healthcare Roman Recommic Area Bull-EC- 1001212021 Spontaneous Healthcare Roman Recommic Area Bull-EC- 100121212021 Spontaneous Healthcare Roman R	n/a - Not reported ICSR
Linknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown -), Vaccination site paraesthesia (n/a - Vaccination	n/a - Not reported ICSR
EU-EC- 30/12/2021 Spontaneous Healthcare Professional EU-EC- 30/12/2021 Spontaneous Healthcare EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - Unknown -) TOZINAMERAN	n/a - Not reported ICSR
EU-EC- 30/12/2021 Spontaneous Healthcare Professional Economic Area Butter Butt	n/a - Not reported ICSR
EU-EC- 10011115137 EU-EC- 1001212021 Spontaneous Healthcare Professional European Economic Area Healthcare Professional European European European Economic Area EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - Unknown -) Wheezing (n/a - Unknown -) Wheezing (n/a - Unknown -) Wheezing (n/a - Unknown -) COMIRNATY [TOZINA Recovered/Resolved Available Fears Specified Profunged Hospitalisation, Other Medically Important Condition) EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - TOZINAMERAN	n/a - Not reported ICSR
EU-EC- 10011115137 Spontaneous Healthcare Professional Economic Area Non Not available EU-EC- 10012115137 Spontaneous Healthcare Professional Economic Area Non Not available Professional Economic Area Not Specified Recovered/Resolved CS - COVID-19 immur Not applicable - [1d - n/a]) EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - TOZINAMERAN)	n/a - Not reported ICSR
10011115137 Professional European Economic Area Professional Eur	n/a - Not reported ICSR
EU-EC- 30/12/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Dizziness (n/a - TO7INAMFRAN	COVID-
10011115140 Professional European European Conomic Professional European Professional Euro	
Area Hypotension (n/a - Recovered/Resolved -), applicable - [1d - n/a Intramuscular])	•
Pain (n/a - Recovered/Resolved -),	
Sensitive skin (n/a - Recovered/Resolved -),	
Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	
Vision blurred (n/a - Recovered/Resolved	
EU-EC- 30/12/2021 Spontaneous Healthcare Professional European Location (Section 1997) Professional Location (Section 1997) Professi	
Economic 19 immunisation - Nc Area Inflammation (n/a - applicable - [1d - n/a Unknown -), Intramuscular])	
Micturition urgency (n/a - Unknown - Other Medically Important Condition),	
Oedema (n/a - Unknown -),	
Pain (n/a - Unknown -),	
Photopsia (n/a - Unknown -),	
Pruritus (n/a - Unknown -),	
Sensitive skin (n/a - Unknown -),	
Urinary incontinence (n/a - Unknown - Other Medically Important Condition),	
Vaccination site erythema (n/a - Unknown -)	
EU-EC- 30/12/2021 Spontaneous Healthcare Professional European Economic Specified Spec	
Area Dizziness (n/a - applicable - [1d - n/a Unknown -), Intramuscular])	
Fatigue (n/a - Unknown -),	
Nausea (n/a - Unknown -),	
Pain (n/a - Unknown -),	
Seizure (n/a - Unknown - Other Medically Important Condition),	

										Sensitive skin (n/a -			
EU-EC- 10011115161	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Caused/Prolonged			
EU-EC- 10011115167	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011115172	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011115193	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Insomnia (n/a - Unknown -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
	2011-11-11					145 :-				Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011115217	30/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

			I	Economic	I		I		I	- Other Medically	Not applicable - [1d - n/a -	I	1
EU-EC- 10011115219	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Paraesthesia (n/a -		Not reported	ICS
										Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition),			
EU-EC- 10011115307	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tachycardia (n/a - Unknown -) Skin reaction (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011115310	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Unknown -), Crying (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Dyspnoea (n/a - Unknown -),			
										Hypothermia (n/a - Unknown - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Unknown -),			
										Oxygen saturation decreased (n/a - Unknown -), Paraesthesia (n/a -			
										Unknown -), Respiratory distress (n/a - Unknown -			
EU-EC-	30/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Other Medically Important Condition) Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011115739			Professional	Economic Area	available	Years				Pain (n/a - Unknown	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10011116058	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE] (C - Gastrointestinal pain - n/a - [n/a - n/a - n/a])	ICS
										Dizziness postural (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Headache (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Syncope (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10011116064	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available		Not Specified	Male	No	Hyperhidrosis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
				Area						Syncope (1d - Recovered/Resolved - Other Medically Important Condition),	n/a])		
EU-EC- 10011116289	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Vision blurred (n/a - Unknown -) Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
			. TOTESSIONAL	, 11 - CG						Headache (n/a - Not Recovered/Not Resolved -),	~J/		

										Recovered/Not			
EU-EC- 100111116317	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011116334	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 100111116335	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition), Nausea (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
EU-EC-	20/12/2021	Chontonoous	Haaltheara	Non	Not	12-17	Not	Mala	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Net reported	ICCD
10011116341	30/12/2021	Spontaneous	Professional	Non European Economic Area	available	Years	Not Specified	Male	INO	decreased (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved			
EU-EC- 10011116730	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
				Area						Decreased appetite (n/a - Not Recovered/Not Resolved -),	applicable - [1d - n/a - Intramuscular])		
										Eye irritation (n/a - Not Recovered/Not Resolved -),			
										Eye pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-	20/12/2021	Constant	1114	Non	Ni-t	12.17	Nick	NA-1-	N.	Vomiting (n/a - Not Recovered/Not Resolved -)	COMPNAT/ (TOTMAMERAN)	CHANGACTNE ICHANGACINE	Tech
100111116734	30/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(4d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a])	ICSR
										Orthostatic hypotension (4d - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)			

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EU-EC- 100111116806	30/12/2021	Spontaneous	Non Healthcare Professional	European	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 100111116820	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Lymphadenopathy (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	ICS
										Pain in jaw (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 100111116856	30/12/2021	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 Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a -	ICS
EU-EC- 10011116893	30/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	n/a - [n/a - n/a - n/a])	ICS
			Professional	Area			·			Injection site inflammation (n/a - Recovering/Resolving -),	Not applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Recovering/Resolving -),			
										Injection site swelling (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011117012	30/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011117549	30/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICS
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),			
										Menstrual disorder (n/a - Not Recovered/Not Resolved -),			
										Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011117646	30/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011117662		Spontaneous	Healthcare Professional	Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICS
EU-EC- 10011118200	30/12/2021	Spontaneous	Healthcare Professional		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])	Not reported	ICSI
										Vaccination failure			

										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011118643	30/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Amnesia (n/a - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Balance disorder (n/a - Not Recovered/Not Resolved -),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])		
										Disorientation (n/a - Recovered/Resolved -),			
										Disturbance in attention (n/a - Recovered/Resolved -),			
										Gait disturbance (n/a			
										Recovered/Resolved -),			
										Memory impairment (n/a -			
										Recovered/Resolved -),			
										Speech disorder (n/a - Recovered/Resolved			
	30/12/2021	Spontaneous			Not	12-17	Not	Female	No	-) C-reactive protein	COMIRNATY CONCENTRATE	Not reported	ICSR
10011118644			Professional	Economic Area	available	Years	Specified			increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]		
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [n/a3mL - Intramuscular])		
										Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 100111118671	30/12/2021	Spontaneous	Healthcare		Not availab l e	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011118836	30/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Hypotension (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Loss of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Oculogyric crisis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Partial seizures (1min			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
				_						Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011118868	30/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Asthenia (2wk - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
										Myalgia (2wk - Recovered/Resolved -),	- Intramuscular])		
										Pain in extremity (2wk - Recovered/Resolved -),			
										Swelling (2wk - Recovered/Resolved -)			
EU-EC- 10011120031	30/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Dysphagia (n/a - Unknown -), Oropharyngeal pain	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>

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EU-EC-	30/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No		COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10011120038		·	Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition), Monoplegia (n/a -	(S - n/a - n/a - [n/a - n/a - Intramuscular])	·	
										Unknown - Other Medically Important			
EU-EC- 10011120075	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
										Altered state of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Aphasia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dysarthria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011120101	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition), Macroglossia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d3mL - Intramuscular])		<u>ICS</u>
										Unknown - Other Medically Important Condition)			
EU-EC- 10011120120	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (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	ICSF
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011120121	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved			
EU-EC- 10011120137	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Febrile convulsion	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Interpress days)	Not reported	ICSR
										(n/a - Unknown -), Generalised tonic- donic seizure (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		

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										Incontinence (n/a - Unknown -), Paralysis (n/a -			
										Unknown - Other Medically Important			
EU-EC-		Spontaneous		Non	Not	12-17	Not	Male	No	Condition) Chills (n/a -	TOZINAMERAN	Not reported	ICSR
10011120163			Professional	European Economic	available	Years	Specified			Unknown -),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not		
				Area						Immunisation (n/a - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Pyrexia (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011120180	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Blood pressure decreased (n/a - Unknown -),			
										Brain natriuretic peptide increased (n/a - Unknown -),			
										Delirium febrile (n/a - Unknown - Other Medically Important Condition),			
										Diarrhoea (n/a - Unknown -),			
										Erythema (n/a - Unknown -),			
										Gastrointestinal disorder (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Inflammation (n/a - Unknown -),			
										Kawasaki's disease (n/a - Unknown - Other Medically Important Condition),			
										Mucosal disorder (n/a - Unknown -),			
										Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Ocular hyperaemia (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -),			
										Systemic inflammatory response syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important			
										Condition), Thrombocytopenia (n/a - Unknown - Other Medically			
EU-EC-	30/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Important Condition) Conversion disorder	TOZINAMERAN	Not reported	ICSR
10011120181				European Economic Area	available	Years	Specified			(n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	,	
										Dizziness (n/a - Unknown -),			
										Vomiting (n/a - Unknown -)			
EU-EC- 10011120187		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>

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											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Paraesthesia (n/a - Unknown - Other Medically Important Condition),			
											Syncope (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011120189	30/12/2021	Spontaneous	Professional	Non European Economic Area	Not available		Not Specified	Female	No	Syncope (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
											Unknown - Other Medically Important Condition), Vision blurred (n/a -	Intramuscular])		
	EU-EC-	30/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Unknown -) Cardio-respiratory	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10011120193	30/12/2021	Spontaneous	Professional		available	Years	Specified	Plate	140	arrest (n/a - Fatal - Results in Death, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSIX
											Drowning (n/a - Fatal - Results in Death, Other Medically Important Condition)			
	EU-EC- 10011120198	30/12/2021	Spontaneous	Professional	Non European Economic Area	Not available		Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
											Chills (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Headache (n/a - Unknown - Other Medically Important Condition),			
											Hypertension (n/a - Unknown - Other Medically Important Condition),			
											Hypoaesthesia (n/a - Unknown - Other Medically Important Condition),			
											Hypoaesthesia oral (n/a - Unknown - Other Medically Important Condition),			
											Nausea (n/a - Unknown - Other Medically Important Condition),			
											Pain (n/a - Unknown - Other Medically Important Condition),			
											Paraesthesia (n/a - Unknown - Other Medically Important Condition),			
											Photopsia (n/a - Unknown - Other Medically Important Condition),			
											Rhinitis (n/a - Unknown - Other Medically Important Condition),			
											Sensitive skin (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011120206	30/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	-),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
											Dehydration (n/a - Recovering/Resolving -), Dizziness (n/a -	Intramuscular])		
											Recovering/Resolving -), Fatigue (n/a -			
											Recovering/Resolving			

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										-), Hypotension (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011120211	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown -), Conversion disorder (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014 (X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/EP1908/2015, INF-180), INFLUENZA VACCINE] (S - Influenza - Not		ICSF
EU-EC- 10011120245	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	

										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tinnitus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tinnitus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Vomiting (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10011120252	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Other Medically Important Condition) Syncope (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011120283	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	n/a]) COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC-		Spontaneous Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Hypoaesthesia (n/a - Recovered/Resolved -), Muscular weakness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -) Asymptomatic	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC- 10011120610	30/12/2021	pontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	remale	INO	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSK
EU-EC- 10011120653	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

		I				I				Other Medically			ı
EU-EC- 10011120818	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011120867	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011120953	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011121143	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011121209	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),			
										Nasal congestion (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pulmonary embolism (1d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition),			
										Testicular pain (1d - Recovered/Resolved - Other Medically Important Condition)			
10011121236		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	ICSR
10011121243		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011121270	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			

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EU-EC- 10011121574	30/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (18d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (18d - Not Recovered/Not Resolved -),			
										Fatigue (18d - Not Recovered/Not Resolved -),			
										Hypotonia (18d - Not Recovered/Not Resolved -),			
										Somnolence (18d - Not Recovered/Not Resolved -)			
EU-EC- 10011121774	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC-	30/12/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Hospitalisation) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
10011121872			Healthcare Professional	European Economic Area	available	Years	Specified			- Fatal - Results in Death, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Abnormal faeces (n/a - Fatal - Results in Death),			
										Anaemia (n/a - Fatal - Results in Death),			
										Anaphylactic reaction (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Defaecation disorder (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Dizziness (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Fatigue (n/a - Fatal - Results in Death),			
										Lung disorder (n/a - Fatal - Results in Death),			
										Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Nerve injury (n/a - Fatal - Results in Death),			
										Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Shock (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Vomiting (n/a - Fatal			
EU-EC- 10011121920	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Results in Death) Chills (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (1d - Not Recovered/Not Resolved -),			
										Influenza (1d - Not Recovered/Not Resolved -),			
										Limb discomfort (1d - Not Recovered/Not Resolved -),			
										Malaise (1d - Not Recovered/Not Resolved -),			
										Pyrexia (1d - Not Recovered/Not Resolved -),			
										Somnolence (1d - Not Recovered/Not Resolved -),			
I	I	I	I	I	I	I	I	I	l	Tremor (1d - Not	I		1 1

										Recovered/Not Resolved -)			
EU-EC- 10011121946	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pharyngeal erythema (45d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Caused/Prolonged Hospitalisation),			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Systemic lupus erythematosus (38d			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Thrombocytopenic purpura (45d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011121977	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pleurisy (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Viral infection (n/a - Unknown -)			
EU-EC- 10011121995	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness (n/a - Unknown - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Pyrexia (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10011122029	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Disease recurrence (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved -)			

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EU-EC- 10011122083	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Menstruation delayed (2d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved			
EU-EC- 10011122135	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Feeling hot (0d - Recovered/Resolved -),			
										Hyperhidrosis (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved			
EU-EC- 10011122199	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (2d - Recovered/Resolved -),			
										Vaccination site pain (2d - Recovered/Resolved			
EU-EC- 10011122248	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (12d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (12d - Recovered/Resolved	, , ,		
EU-EC- 10011122268	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (0d - Recovering/Resolving -),			
										Pyrexia (0d - Recovering/Resolving			
EU-EC- 10011122372	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Limb discomfort (2d - Recovered/Resolved			
										Pyrexia (2d - Recovered/Resolved			
EU-EC- 10011122376	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (1d - Unknown -), Paraesthesia (1d -			
EU-EC- 10011122540	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown -) Rash (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
			Professional	Alea						Rash erythematous	- 11/a - 11/a] <i>)</i>		
										Recovered/Resolved -), Urticaria (1d -			
EU-EC- 10011122580	30/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Chills (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional							-), Dizziness (1d - Recovering/Resolving	- n/a - n/a])		
										-), Headache (1d - Recovering/Resolving			
										-), Limb discomfort (1d			
										Recovering/Resolving -),			
EILEC	30/12/2021	Spontaneous	Healthcare	Non	Not	12.17	Not	Male	No	Vomiting (1d - Recovering/Resolving -)	COMIDNATY (TOZIAJAMEDAA)	Not reported	ICCP
EU-EC- 10011122771	30/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	nvoc reported	ICSR

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EU-EC-	30/12/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Important Condition) Blood pressure	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011122778			Professional	European Economic Area	available	Years	Specified				(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Headache (n/a - Recovering/Resolving			
EU-EC- 10011122789	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypersensitivity (n/a - Unknown - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Pruritus (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011122981	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (7wk - Recovered/Resolved -), Pericarditis (7wk -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011123205	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC-	30/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	-) Asthmatic crisis (n/a	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011123217			Healthcare Professional	Economic Area	available	Years					(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Recovering/Resolving -)			
EU-EC- 10011123258	30/12/2021	Spontaneous	Healthcare	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])	Not reported	ICSR
EU-EC- 10011123380	30/12/2021	Spontaneous	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011123394	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011123405	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011123507	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abnormal uterine bleeding (32d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Anaemia (n/a - Unknown - Other Medically Important Condition),			

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										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011123587	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Diplopia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Respiratory distress (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011123670	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										-), Headache (2d - Recovered/Resolved -),			
										Limb discomfort (2d - Recovered/Resolved -), Pyrexia (2d -			
										Recovered/Resolved			
EU-EC- 10011123717	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved			
EU-EC- 10011123719	30/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
100111123/19			Professional		avanable	ICOIS				Injection site pain (1d - Unknown -), Nausea (1d -	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC-	30/12/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Unknown -) Haematoma (11d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011123917			Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved -), Pain in extremity (11d - Not Recovered/Not	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Resolved -), Rash (11d - Not Recovered/Not Resolved -)			
EU-EC- 10011124020	30/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR

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				Professional	Area						Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	- n/a - n/a])		
											Headache (n/a - Not Recovered/Not Resolved -),			
											Limb discomfort (n/a - Not Recovered/Not Resolved -)			
	:U-EC- 0011124021	30/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
											Dizziness (2d - Recovered/Resolved -),			
											Fatigue (2d - Recovered/Resolved -),			
											Influenza like illness (2d - Recovered/Resolved -),			
											Vaccination site pain (2d -			
	:U-EC- 0011124061	30/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Vaccination site reaction (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	<u>ICSR</u>
E	U-EC-	30/12/2021	Spontaneous	Professional Non	Area European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Rash (n/a -	- n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
E	0011124283 EU-EC- 0011124317	30/12/2021	Spontaneous	Professional Non	Area European	available Not available	Years 12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Dizziness (1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
ľ	.0011124317				Area	available	rears				-), Dizziness (2d -	- n/a - Intravenous (not otherwise specified)])		
											Recovered/Resolved -), Dizziness (3d -			
											Recovered/Resolved -), Fatigue (2d -			
											Recovered/Resolved -), Feeling hot (1d -			
											Recovered/Resolved -),			
											Head discomfort (1d - Recovered/Resolved -),			
											Head discomfort (2d - Recovered/Resolved			
											-), Head discomfort (3d			
											Recovered/Resolved			
											Injection site pain (3d - Recovered/Resolved -),			
											Injection site swelling (3d - Recovered/Resolved -)			
	:U-EC- 0011124326	30/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Chills (7d - Not Recovered/Not Resolved -),			
											Oropharyngeal pain (7d - Not Recovered/Not Resolved -),			
											Pyrexia (7d - Not Recovered/Not Resolved -)			
	:U-EC- 0011124328	30/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Injection site pain (1d - Recovered/Resolved			
											-), Injection site swelling (1d -			
											Recovered/Resolved -),			

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										Pyrexia (1d - Recovered/Resolved -),			
										Throat irritation (1d - Recovered/Resolved -),			
										Vomiting (0d - Recovered/Resolved			
EU-EC- 10011124441	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Limb discomfort (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Pruritus (n/a - Not Recovered/Not Resolved -),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011124479	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (2d - Recovered/Resolved -), Pain (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10011124493	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (2d - Recovering/Resolving -)			
EU-EC- 10011124540	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011124816	30/12/2021	Spontaneous	Healthcare	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011124908		Spontaneous	Professional	Economic Area	Not available	Years	Not Specified	Male	No	Blood pressure increased (195min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	ICSR
EU-EC- 100111124920	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Chest pain (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	<u>ICSR</u>
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain in jaw (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

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										Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Sinus arrhythmia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011125015	30/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	<u>ICSR</u>
EU-EC- 10011125131	30/12/2021	Spontaneous	Non Healthcare	European	Not available	12-17 Years	Adolescent	Female	No	Myalgia (5d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011125265	30/12/2021	Spontaneous	Non Healthcare	European	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (40d - Not Recovered/Not Resolved -),	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Gastrointestinal pain (40d - Not Recovered/Not Resolved -),			
										Injection site pain (40d - Not Recovered/Not Resolved -),			
										Nausea (40d - Not Recovered/Not Resolved -)			
EU-EC- 10011125420		Spontaneous	Non Healthcare Professional				Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d - Recovering/Resolving -),			
										Malaise (1d - Recovering/Resolving			
EU-EC- 10011125497	30/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Conjunctivitis (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hordeolum (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011125567	30/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),			
										Somnolence (1d - Recovered/Resolved -)			
EU-EC- 10011125866	30/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	(10d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (10d - Recovered/Resolved -)			
EU-EC- 10011125890	30/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	· ·	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (9d - Not			

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										Recovered/Not Resolved -), Epilepsy (9d - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (7d - Not Recovered/Not Resolved -),			
										Petit mal epilepsy (9d - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011125985	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011126114	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011126171	30/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Faeces soft (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	30/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Malo	No	Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) Headache (0d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011126681	30/12/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	Male	NO		(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSK
										Nausea (0d - Recovering/Resolving -),			
										Vomiting (0d - Recovering/Resolving -)			
EU-EC- 10011126713	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved -), Fatigue (0d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Limb discomfort (2d - Not Recovered/Not			
										Resolved -), Pain in extremity (2d - Not Recovered/Not			
EU-EC- 10011126833	30/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional							Resolved -), Injection site pain (n/a - Not	- n/a - n/a])		
										Recovered/Not Resolved -),			
										Petechiae (n/a - Not Recovered/Not Resolved -),			
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011126940	30/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a -	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	,	[n/a - n/a - n/a])	
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
EU 50	20/42/22	Const.	New	F	NI-L	12.4=	A 4-1	F :	N.	Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMPNATATOR	No.	Tees
EU-EC- 10011127052	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Chills (27d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Cough (27d - Not Recovered/Not Resolved -),			
										Dizziness (27d - Not			

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											Recovered/Not Resolved -), Influenza (27d - Not Recovered/Not			
											Resolved -), Influenza like illness (27d - Not Recovered/Not			
											Resolved -), Injection site pain (27d - Not Recovered/Not			
											Resolved -), Injection site swelling (27d - Not Recovered/Not Resolved -),			
											Lymphadenopathy (27d - Not Recovered/Not Resolved -),			
											Oropharyngeal pain (27d - Not Recovered/Not Resolved -)			
	U-EC- .0011127318	30/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	<u>ICSR</u>
					Economic Area							19 immunisation - Not applicable - [Id - n/a - Intramuscular])		
											Pain (n/a - Recovering/Resolving -),			
											Sensitive skin (n/a - Recovering/Resolving -), Tinnitus (n/a -			
											Recovering/Resolving -), Vision blurred (n/a -			
											Recovering/Resolving			
1	EU-EC- .0011127494	30/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Blood creatine phosphokinase increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Chest pain (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Dyspnoea (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Electrocardiogram ST segment elevation (n/a - Recovered/Resolved			
											- Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Insomnia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Nausea (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
- 1											1 lospitalisation),			

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										- Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin I increased (7d - Recovered/Resolved			
EU-EC-	30/12/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	- Caused/Prolonged Hospitalisation) Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011127583			Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011127657		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSI
EU-EC- 10011128087	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011128111	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (65min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intradermal])	Not reported	ICSF
										Incorrect route of product administration (n/a - Unknown -),			
										Syncope (65min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011128167	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Malaise (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC-	30/12/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Urticaria (2d -	COMIRNATY [TOZINAMERAN]		ICSR
10011128180			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Nasopharyngitis - Not applicable - [4d - n/a - n/a])	
EU-EC- 10011128192		Spontaneous	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} - Unknown])		ICSR
EU-EC- 10011128268	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011101293	29/12/2021	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 - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011101532	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Limb discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011101629	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011101646	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			

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										Hyperthermia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011101674	29/12/2021	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 - 1{DF} - Intramuscular])	Not reported	ICSR
										Face oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lip blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vulvovaginal erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011101759	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Abdominal pain (n/a - Recovering/Resolving -),			
										Diarrhoea (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011101942	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a45mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011102419	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Systemic lupus erythematosus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011102428	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Sluggishness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011102448	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESLORATADINE] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral])	ICSR
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											Aggression (n/a - Recovering/Resolving - Life Threatening),			
											Altered state of consciousness (0d - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
											Condition aggravated (n/a - Unknown - Life Threatening, Other Medically Important Condition),			
											Irritability (n/a - Unknown -),			
											Malaise (30h - Recovered/Resolved -),			
											Neutropenia (n/a - Unknown - Life Threatening, Other Medically Important Condition),			
											Oxygen saturation decreased (30h - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
											Physical deconditioning (n/a - Unknown - Life Threatening, Other Medically Important Condition),			
											Suicide attempt (n/a			
											Recovering/Resolving - Life Threatening, Other Medically Important Condition),			
											Tachycardia (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition),			
											Vomiting (2d - Recovered/Resolved - Life Threatening, Other Medically Important Condition)			
	EU-EC- 10011102480	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	Not applicable - [n/a - n/a - Intramuscular])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
											Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)		1ya - [1ya - 1ya - 1ya])	
	EU-EC- 10011102774	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
											Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Neck pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
	EU-EC- 10011103100	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011103133	29/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR

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				Area						Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	Intramuscular])		
										Important Condition)			ļ
EU-EC- 10011103352		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	(n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])		ICSR
EU-EC- 10011103367	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011103723	29/12/2021	Spontaneous	Healthcare	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])	Not reported	ICSR
EU 50						10.15				Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011103850	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011103852	29/12/2021	Spontaneous	Non Healthcare Professional	Non 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	ICSR
										Chills (n/a - Unknown - Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	20/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Hyperhidrosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011103854	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	Years	Specified	remale	INO		(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving			

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	EU-EC- 10011103859	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											joint syndrome (n/a - Unknown -)			
	EU-EC- 10011103867	29/12/2021	Spontaneous	Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	<u>ICSR</u>
					Area						Nausea (n/a - Unknown -),	applicable - [1d - n/a - Intramuscular])		
											Pain (n/a - Unknown -),			
											Sensitive skin (n/a - Unknown -),			
											Syncope (n/a - Unknown - Other Medically Important Condition),			
	F.1. F.0	20/12/2021					10.17				Vision blurred (n/a - Unknown -)			1000
	EU-EC- 10011103875	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
											Pyrexia (n/a - Recovered/Resolved - Other Medically			
	EU-EC- 10011103879	29/12/2021	Spontaneous		Non	Not available		Not Specified	Female	No	Important Condition) Acetonaemic vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
	10011103679				European Economic Area	avallable	rears	Specified			- Caused/Prolonged Hospitalisation),	Not applicable - [1d - n/a - Unknown])		
											Back pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Chest discomfort (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Chest pain (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Injection site swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Pyrexia (12d - Recovered/Resolved			
	EU-EC-	29/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	- Caused/Prolonged Hospitalisation) Platelet count	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10011103887	,,	,	Professional		available	Years	Specified			decreased (57h -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
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										Thrombocytopenic purpura (n/a - Unknown -)			
EU-EC- 10011103888	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011103909	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (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	ICS
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -)			
EU-EC- 10011103916	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011103917	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Cerebral haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Haemangioma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Nausea (161h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Unresponsive to stimuli (9630min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										White blood cell count increased (n/a			
										Recovered/Resolved Other Medically Important Condition			
EU-EC- 10011103918	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Syncope (n/a - Unknown - Other Medically Important			
EU-EC- 10011103919	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Muscle twitching (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICS

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										Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011103920	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				7.1.00						Nausea (n/a - Recovering/Resolving -),	Intramuscular])		
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011103923	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Motor dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011103936	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Joint hyperextension (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Postictal state (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Salivary hypersecretion (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011103938	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Dizziness (n/a - Unknown - Other Medically Important Condition),	, in the second		
										Paraesthesia (n/a - Unknown - Other Medically Important Condition),			
										Pharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Tonsillar hypertrophy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011103943		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011103953	29/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

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				Economic Area						Asthenia (n/a - Unknown -),	19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Dizziness (n/a - Unknown -),	27		
										Fatigue (n/a - Unknown -),			
										Myalgia (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011103955	29/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Bradycardia (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Myocarditis (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	20/12/2021	Chantanagus	Nen	Non	Not	12.17	Not	Mala	No	Palpitations (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMPONATY FTOZINAMEDANI	Net reported	ICC
10011103957	29/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Gait disturbance (n/a - Unknown -),			
										Headache (n/a - Recovered/Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011103992	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011104004	29/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICS
				Area						Dyspnoea (n/a - Recovered/Resolved -),	applicable - [1d - n/a - Intramuscular])		
										Headache (n/a - Recovered/Resolved -),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011104006	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Anaphylactic shock (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Bronchospasm (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged			

												_	
										Important Condition), Dyspnoea (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pruritus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Respiratory distress (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Sensitive skin (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011104019	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (35min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011104020	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011104030	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	2		
EU-EC- 10011104032	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (362h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE	ICSR
										Headache (370h - Recovered/Resolved - Caused/Prolonged Hospitalisation),		STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181),	
										Microcytic anaemia (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),		A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN	
										Muscular weakness (362h - Recovered/Resolved - Caused/Prolonged Hospitalisation)		(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Influenza immunisation - n/a - [n/a - n/a - n/a])	
EU-EC- 10011104228	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		ICSR

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										Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
	9/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Pain (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Sensitive skin (n/a - Unknown -),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
1.50	0/10/2021					12.17				Vision blurred (n/a - Unknown -)	TOTTUMED AN		100
I-EC- 29 011104346	9/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disorientation (1min - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>IC</u>
										Dizziness (n/a - Unknown -),	Intramuscular])		
										Pain (n/a - Unknown -),			
										Sensitive skin (n/a - Unknown -),			
										Syncope (1min - Recovered/Resolved - Other Medically Important Condition)			
011104348		Spontaneous	Healthcare Professional	Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		IC
-EC- 011104349	9/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>IC</u>
I-EC- 011104359	9/12/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>I(</u>
D-EC- 011104360	9/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oedema (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
										Pruritus (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition),			
										Sensitive skin (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EC- 011104368	9/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	IC
				Area						Chills (n/a - Unknown -), Dyspnoea (n/a -	applicable - [1d - n/a - Intramuscular])		
										Unknown -), Inflammation (n/a -			
I										Unknown -), Irritability (n/a -			
										Lymphadenopathy (n/a - Unknown -),			
				1									
										Mobility decreased (n/a - Not Recovered/Not Resolved -)			
										(n/a - Not			

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										Respiratory distress (n/a - Unknown - Other Medically Important Condition),			
										Sensitive skin (n/a - Unknown -), Vaccination site			
										erythema (n/a - Unknown -),			
EU-EC-	20/12/2021	Chantanasus	I lookk as us	Non	Not	12.17	Not	Male	No	Vaccination site oedema (n/a - Unknown -)	TOZINAMEDANI	Nat you out od	ICCD
10011104370	29/12/2021	Spontaneous	Professional	Non European Economic Area	available	12-17 Years	Not Specified	Male	NO	Accidental overdose (n/a - Unknown -), Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Unknown -), Headache (n/a -			
EU-EC- 10011104393	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Angioedema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
FILEC	20/12/2021	Constitution	Uzalihana	Neg	Net	12.17	Net	M-I-	N-	Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMPANY FROM MATERIAL		ICCD
EU-EC- 10011104399	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (42d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	<u>ICSR</u>
										Myocarditis (42d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011104405	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cellulitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Left ventricular failure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericardial effusion			
										rericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a -			
										. cricardius (il/a -			

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EU-EC- 10011104445	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICS
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011104541	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Headache (n/a - Recovering/Resolving -)			
EU-EC- 10011104543	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (3h - Recovered/Resolved -), Syncope (90min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011104559	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Febrile convulsion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	and a second of		
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
:U-EC- 0011104571	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	VACCINE MODERNA (CX- 024414)] (N - COVID-19	ICS
										Asthenia (8h - Recovered/Resolved -),	Intramuscular])	immunisation - Not applicable - [1d - n/a - n/a])	
										Decreased appetite (n/a - Unknown -),			
										Fatigue (n/a - Unknown -),			
										Headache (8h - Recovered/Resolved -),			
										Musculoskeletal pain (8h - Recovered/Resolved -),			
										Nausea (8h - Recovered/Resolved -),			
										Pyrexia (8h - Recovered/Resolved -),			
										Spinal pain (150min - Recovered/Resolved -),			
										Vaccination site pain (n/a - Unknown -),			
										Vomiting (8h - Recovered/Resolved -),			
										Wrong product administered (n/a - Unknown -)			
EU-EC- 10011104584	29/12/2021	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 - Intramuscular])	Not reported	ICS
										Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Chest discomfort (n/a - Unknown - Other Medically Important Condition),			

										Chills (n/a - Unknown - Other Medically Important Condition),			
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Induration (n/a - Unknown - Other Medically Important Condition),			
										Inflammation (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Nodule (n/a - Unknown - Other Medically Important Condition),			
										Oedema (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),			
										Rhinorrhoea (n/a - Unknown - Other Medically Important Condition),			
										Sensitive skin (n/a - Unknown - Other Medically Important Condition),			
										Sleep paralysis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011104598		Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified		No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011104601	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Seizure (5min - Recovered/Resolved - Other Medically Important Condition),			
										Speech disorder (5min - Recovered/Resolved - Other Medically Important Condition),			
										Tremor (5min - Recovered/Resolved - Other Medically Important Condition),			

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										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011104688	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSF
EU-EC- 10011104780	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site lymphadenopathy (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		ICSF
EU-EC- 10011104956	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (2d - Recovered/Resolved -), Dyspnoea (2d - Recovered/Resolved -), Fatigue (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Resolved -), Feeling cold (2d - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved -),			
										Influenza (2d - Recovered/Resolved -), Pain in extremity (2d			
										Recovered/Resolved -), Throat irritation (2d - Recovered/Resolved			
EU-EC- 10011105306	29/12/2021	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])	Not reported	ICSI
EU-EC-	20/12/2021	Chantanagus	Haalthaava	European	Not	12.17	Adelegant	Mala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) Chest discomfort	COMIDNATY (TOZINAMEDANI)	Not vaported	ICCI
10011105517	29/12/2021	Spontaneous	Professional	Economic Area	Not available	12-17 Years	Adolescent	Male	No	(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocardial oedema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin T increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011105534	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10011105537	29/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	(n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSF
				Area						Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	Intramuscular])		
EU-EC- 10011105544	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Myocarditis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011105668	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	GOMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011105882	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lung hyperinflation (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR

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										Condition), Nodule (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10011106001	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Apathy (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
										-), Myalgia (n/a - Recovered/Resolved -),	Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain			
										(n/a - Recovered/Resolved -)			
EU-EC- 10011106037	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	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])	Not reported	ICSR
EU-EC- 10011106448	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10011106584	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovered/Resolved -),			
										Paraesthesia (n/a - Not Recovered/Not Resolved -),			
										Presyncope (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10011106585	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011106619	29/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011106689	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved -),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])		
										Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not			
E11 E0	20/42/2024		None	-	N	12.17				Recovered/Not Resolved -)	COMPNATY (TOTALAMED AND	N. I. and A. I.	T.CCD
EU-EC- 10011106999	12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	i™die	No	Atrial tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	тког герогсеа	ICSR
										SARS-CoV-2 test negative (n/a - Recovered/Resolved With Sequelae - Life Threatening)			
EU-EC-	29/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011107074			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011107549	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011107555	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood immunoglobulin E increased (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	FEXOFENADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a -	ICSR
										Cold sweat (n/a - Recovered/Resolved -),		n/a - Oral])	
										Food allergy (n/a - Unknown -),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved -)			
EU-EC- 10011107560	29/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
				Area						Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a])		
										Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107561	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011107578	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011107581	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			

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EU-EC- 10011107596	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Encephalomyelitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Feeling cold (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Opsoclonus myoclonus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107599	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (45min - Recovered/Resolved -), Hypotension (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (45min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011107603	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107606	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU-EC- 10011107608	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition) Heart rate irregular (n/a - Recovered/Resolved - Other Medically Important Condition),		Not reported	ICSR
										Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	29/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition) Chest discomfort	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
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10011107615			Professional	European Economic Area	available	Years	Specified				(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Chest pain (n/a - Recovering/Resolving -),			
										Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pneumothorax (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011107616	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107621	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Decreased activity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107627	29/12/2021	Spontaneous		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 applicable - [1d - n/a - Intramuscular])		ICSR
										Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Cold sweat (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Contusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Mitral valve prolapse (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically			

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										Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Sinus arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Sinus tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC-		Spontaneous		Non	Not	12-17	Not	Female	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition) Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011107	7655		Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Loss of consciousness (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Recovered/Resolved - Other Medically Important Condition),			
FILES.	20 (42 (2024			Non	No.	42.47	No		N	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMPNAT/ (TOTMAMEDAN)		LCCD
EU-EC- 10011107		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Autonomic neuropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Neck pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Postural orthostatic tachycardia syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Weight decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011107		Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR

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											Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Myocarditis (15d - Recovered/Resolved - Other Medically Important Condition),			
											Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10011107779	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Thrombotic stroke (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 100111107801	29/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Dysstasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Haemolytic anaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Jaundice (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)			
	EU-EC- 10011107939	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Dizziness (n/a - Recovered/Resolved			

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										Recovered/Resolved -)			
EU-EC- .0011108023	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	IC:
:U-EC- .0011108090	29/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hodgkin's disease (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>IC</u>
:U-EC- 0011108230	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown -), Muscle twitching	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
U-EC-	20/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	(n/a - Unknown -) Vasculitis (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	IC
0011108338	29/12/2021	Sportaneous	Professional	Economic Area	available	Years	Specified	remaie	No	Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	100
U-EC- 0011108350	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
U-EC- 0011108372	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Limb discomfort (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Pyrexia (6d - Recovered/Resolved -)			
U-EC- 0011108378	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Local reaction (1d - Recovering/Resolving -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Recovering/Resolving -),			
										Vaccination site pain (1d - Recovering/Resolving -)			
:U-EC- 0011108872	29/12/2021	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])	Not reported	<u>I</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011108918	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cyanosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
										Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Dyspnoea (n/a - Not			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Febrile convulsion (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Increased bronchial secretion (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Respiratory distress (n/a - Not			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- .0011108922	29/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	IC
				Economic Area						Chills (n/a -	19 immunisation - Not applicable - [1d - n/a - Intramuscular])		

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										Dizziness (n/a - Unknown -),			
										Fatigue (n/a - Unknown -),			
										Hypothermia (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Oropharyngeal discomfort (n/a - Unknown -),			
										Oropharyngeal pain (n/a - Unknown -),			
										Palpitations (n/a - Unknown -),			
										Tachycardia (n/a - Unknown -)			
EU-EC- 10011108926	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011108930	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Dizziness (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011108968	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dermatosis (n/a - Unknown - Other Medically Important Condition),	, , , , , , , , , , , , , , , , , , ,		
										Erythema (n/a - Unknown -)			
EU-EC- 10011108978	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
				Area						Asthenia (n/a - Unknown -),	applicable - [1d - n/a - Intramuscular])		
										Disorientation (n/a - Unknown -),			
										Dizziness (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Myalgia (n/a - Unknown -),			
										Nausea (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011108988	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Paraesthesia (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC-	29/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Areflexia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10011109081			Professional	Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition),	(S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])		
										Febrile convulsion (n/a - Unknown - Other Medically Important Condition),			
										Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Muscular weakness (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011109083	29/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hepatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Transaminases increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011109172	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])		
										Electrocardiogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011109296	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a -			
EU-EC- 10011109298	29/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Chest pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not	Not reported	ICSR
				Area						- Caused/Prolonged Hospitalisation), Cough (1wk - Recovered/Resolved	applicable - [n/a3mL - Intramuscular])		
										-), Electrocardiogram			
										ambulatory abnormal (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation),			

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											Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving			
											- Caused/Prolonged Hospitalisation), Pyrexia (1wk - Recovered/Resolved			
											-)			
	EU-EC- 10011109304	29/12/2021	Spontaneous	Professional		Not available		Not Specified	Female	No	- Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
											Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Hypotonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Vaccination site reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Visual field defect (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
	EU-EC- 10011109337	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available		Not Specified	Male	No	Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10011109373	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -), Gait disturbance (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											- Unknown -), Hand deformity (n/a - Unknown -),			
											Vertigo (27d - Recovered/Resolved - Other Medically Important Condition),			
											Vestibular disorder (27d - Recovered/Resolved - Other Medically			
											Important Condition), Vomiting (n/a -			
	EU-EC-	29/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Unknown -) Rash (n/a - Unknown	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
	10011109374	, ,	·	Professional		available		Specified			- Caused/Prolonged Hospitalisation,	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	
											Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation,			
											Other Medically Important Condition),			
											Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10011109377	29/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
					Economic Area						Cough (n/a - Unknown -),	Not applicable - [1d - n/a - Unknown])		
											Dyspnoea (n/a - Unknown -), Headache (n/a -			
			I				1				l			ı

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										Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011109479	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011109540	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown -), Erythema (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Unknown - Other Medically Important Condition),	Intramuscular])		
										Pruritus (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011109603	29/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011109701	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR
										Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [n/a3mL - Intramuscular])		
										Slow response to stimuli (n/a - Unknown - Caused/Prolonged			
EU-EC- 10011109744	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Hospitalisation), Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Heart rate abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocardial hypoxia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important			
										Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation,			
EU-EC-	29/12/2021	Spontancous	Healthcaro	Furonean	Not	12-17	Adolescent	Female	No	Other Medically Important Condition) Angioedema (n/a -	COMIDNATY [TOZINAMEDAN]	Not reported	ICCD
10011109763		Spontaneous	Professional	European Economic Area	Not available	Years				Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL - Intramuscular])		ICSR
EU-EC- 10011109834	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	⊦emale	No	Toxic skin eruption (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011109913	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pneumothorax (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Intermenstrual	COMIRNATY [TOZINAMERAN]	[DOXYCYCLINE,	ICSR

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10011109951			Healthcare Professional	Economic Area	available	Years				bleeding (n/a - Not Recovered/Not Resolved -), Premenstrual syndrome (n/a - Not Recovered/Not Resolved - Other	(S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10011110122	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Medically Important Condition) Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [23d - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011110159	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011110368	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Hypoaesthesia (n/a - Recovered/Resolved -), Lip oedema (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011110466	29/12/2021	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 - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011110590	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011110621	29/12/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011110767	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011110784	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Conjunctival hyperaemia (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fibrin D dimer increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash maculo-papular (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Red blood cell sedimentation rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Serum ferritin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Thrombocytopenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011110831	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011110840	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anal sphincter atony (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Anisocoria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
	l	l	l	l	l	I	l			Bladder sphincter			

EU-EC- 10011110859	29/12/2021	Spontaneous	Healthcare		Not	12-17 Years	Not	Male	No	atony (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bradycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Crepitations (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyskinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Jugular vein distension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation immeasurable (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation immeasurable (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011110979	29/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Application site haemorrhage (4d - Recovered/Resolved -), Injection site erythema (4d - Recovered/Resolved -), Local reaction (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10011110989	29/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (1d - Not Recovered/Not Resolved -)			
EU-EC- 10011110991	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Chills (n/a - Unknown -), Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown -), Headache (n/a -			
										Unknown -), Malaise (n/a -			
										Unknown -), Pyrexia (n/a -			
										Unknown -), Vaccination site pain			
EU-EC- 10011111148	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	(n/a - Unknown -) Herpes zoster (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (7d - Recovered/Resolved -)			
EU-EC- 10011111194	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),			
										Influenza (1d - Recovered/Resolved -),			
										Injection site swelling (1d - Recovered/Resolved -)			
EU-EC- 10011111209	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011111219	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash pruritic (n/a - Recovering/Resolving -)			
EU-EC- 10011111225	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),			
										Influenza (1d - Recovered/Resolved -),			
										Injection site swelling (1d - Recovered/Resolved			
EU-EC- 10011111382	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Feeling hot (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain in extremity (2d			
EU-EC-	20/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Recovered/Resolved -) Myocarditis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011111564	23/12/2021	Spontaneous	Professional	Economic Area	available	Years	Specified	ridic	No	Recovering/Resolving - Caused/Prolonged Hospitalisation)		Not reported	ICSIN
EU-EC- 10011111593	29/12/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011111764	29/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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				Economic Area						Condition), Dizziness postural (2d - Recovered/Resolved - Other Medically Important Condition),	Not applicable - [n/a - n/a - n/a])		
										Hallucination (0d - Recovered/Resolved - Other Medically Important Condition),			
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),			
										Muscular weakness (2d - Recovered/Resolved - Other Medically Important Condition),			
										Paralysis (n/a - Unknown - Other Medically Important Condition), Pyrexia (1d -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011111775	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011111833	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood glucose fluctuation (n/a - Unknown -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011111854	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011111906	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Guillain-Barre syndrome (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011112269	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011112281	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011112297	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a -			
										Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10011112363	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Acidosis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Autonomic nervous system imbalance (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Depressed level of consciousness (2d - Recovered/Resolved			

										- Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Orthostatic intolerance (n/a - Unknown -), Presyncope (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Suggishness (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Suggishness (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Other Medically Important Condition),			
										Vaccination site pain (2d - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10011112379	29/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011112510	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a5mL - Intramuscular])	Not reported	ICSR
EU-EC-	20/12/2021	Spontaneous	1114	Non	Not	12-17	Not	Male	No	Unknown - Other Medically Important Condition) Dizziness (n/a -	TOZINAMERAN	Not reported	ICSR
EU-EC- 10011112528		Spontaneous	Professional	European Economic Area	Not available	Years 12-17 Years	Specified Not Specified		No	Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Paraesthesia (n/a - Recovered/Resolved -), Sensitive skin (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -) Blood pressure decreased (n/a - Recovered/Resolved -) Blood pressure decreased (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -		ICSR

				Economic							Not applicable - [1d - n/a -		
EU-EC- 10011113158	29/12/2021	Spontaneous	Healthcare Professional	Area European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation), Anaphylactic reaction	Intramuscular]) (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Gaze palsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Unresponsive to stimuli (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Wheezing (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011113174		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])		ICSR
EU-EC- 10011113241	29/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vision blurred (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011113423	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved -), Vaccination site reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011113458	29/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011113462	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (4d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011113475	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	(6d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011113488	29/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Erythema (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Immunisation (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Injection site mass (n/a - Not Recovered/Not			

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										Resolved - Disabling, Other Medically Important Condition),			
										Interchange of vaccine products (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Off label use (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Pain (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Peripheral swelling (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10011113630	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Dyspnoea (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Hyperhidrosis (n/a - Unknown -),			
										Nausea (n/a - Unknown -), Respiratory distress			
										(n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown -)			
EU-EC- 10011113753	29/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Asthenia (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011113801	29/12/2021	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011088808	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (8d - Recovered/Resolved -)			
EU-EC- 10011089124	28/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -),			
										Extrasystoles (n/a - Not Recovered/Not Resolved -),			
										Fibrin D dimer increased (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not			

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										Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -),			
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011089241	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Diarrhoea (n/a - Recovered/Resolved -),			
										Dizziness (n/a - Recovered/Resolved -),			
										Fatigue (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -),			
										Muscle spasms (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
EIL EC	20/12/2021	Chambanasus	I I a a lith a a wa	F	Not	12.17	Nat	Mala	No	Rash (n/a - Recovered/Resolved -)	COMIDNATY (TOZINAMEDANI)	Not reported	ICCD
EU-EC- 10011089453 EU-EC-		Spontaneous Spontaneous	Professional	European Economic Area Non	Not available Not	12-17 Years	Not Specified Not	Male Male	No No	Headache (3d - Recovered/Resolved -) Pericarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR ICSR
10011089914			Professional	European Economic Area	available	Years	Specified			Not Recovered/Not Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	·	
EU-EC- 10011089917	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011089925	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011090068	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011090198	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011090199	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	<u>ICSR</u>
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011090200	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011090223	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>

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EU-EC- 10011090305	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Dizziness (n/a - Recovering/Resolving -),			
										Hypoaesthesia (n/a - Recovering/Resolving -),			
										Muscular weakness (n/a - Recovering/Resolving			
										Syncope (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10011090362	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Influenza like illness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional	Area						-), Lymphadenopathy	Not applicable - [2s3mL - Intramuscular])		
										(2d - Recovered/Resolved -),			
										Peripheral swelling (2d - Recovered/Resolved -),			
										Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10011090859	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved -)			
EU-EC- 10011090919	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011091102	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
FU 50	20/42/2021				Not	12.47	Alder		N.	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPANY (TOTAL MEDIAN)	N	TOOD
EU-EC- 10011091280	28/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011091466	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011091887	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
				Area						Eosinophilia (n/a - Unknown -), Petechiae (n/a -	n/a])		
										Unknown -), Rhinitis (n/a - Unknown -),			
										Thrombocytopenia (n/a - Unknown - Other Medically			
EU-EC- 10011091910	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
										Chills (n/a - Recovered/Resolved			
										Myocarditis (n/a - Recovered/Resolved - Other Medically			
										Important			

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										Condition), Troponin T increased (n/a - Recovered/Resolved -)			
EU-EC- 10011092090	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092121	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Chills (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolving -), Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092173	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Inappropriate schedule of product administration (n/a - Unknown -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011092196		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (1d - (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC- 10011092200	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011092221	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Malaise (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PARACETAMOL] (C - Headache, Pyrexia - n/a - [n/a - n/a - Oral])	ICSR

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										Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Urticaria (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10011092228	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092252	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (16min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092255	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011092276	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092285	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved -), Syncope (n/a -			
EU 50	20/12/2021					10.17				Recovered/Resolved - Other Medically Important Condition)			1000
EU-EC- 10011092290	28/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Immunisation (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Muscular weakness (n/a - Unknown -),			
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown -)			
EU-EC- 10011092311		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011092320	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011092364	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Seizure (10s - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011092381	28/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Malaise (n/a - Recovered/Resolved -),	n/a])		
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011092383	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			

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Build		28/12/2021	Spontaneous	Healthcare	European Economic	Not available			Female	No	(n/a - Unknown - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
Secretary Secr											Recovered/Not Resolved - Other Medically Important			
Big											Not Recovered/Not Resolved - Other Medically Important			
Bioconservictors Bioconservi											Recovered/Not Resolved - Other Medically Important			
Public P											Recovered/Not Resolved - Other Medically Important			
Display											Recovered/Not Resolved - Other Medically Important			
EU-C- 1011/19/24/25 26/12/2022 Sportlaneous Neather Next		28/12/2021	Spontaneous		European Economic				Female	No	Unknown -),	(S - COVID-19 immunisation - Not applicable - [1d3mL -	Not reported	ICSR
EU-SC 2012/2021 Spontaneous Insultations Not professional Europeanus Not professional					Aica						(n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important	Internascular jy		
Professional European and European and European and European and Professional Cardinal Cardinal Professional Cardinal Cardinal Professional Cardinal Cardinal Professional Cardinal Card		28/12/2021	Spontaneous		European Economic				Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011092428 Sportaneous Healthcare Non Professional Section Recommendation Professional Section Recommendation Professional Section Recommendation Professional Section Recommendation Recommendat		28/12/2021	Spontaneous		European Economic				Male	No	increased (0d - Recovered/Resolved - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011092422 Bell-EC- 10011092492 Bell-EC- 10011092493 Bell-EC- 10011092493 Bell-EC- 10011092494 Be														
ELI-EC- 11011092492 28/12/2021 Spontaneous Non Healthcare Professional Area EU-EC- 11011092749 Resching - Caused/Protonged Healthcare Professional Resching - Caused/Protonged Healthcare Professional Area EU-EC- 11011092749 Resching - Caused/Protonged Healthcare Professional Resching - Caused/Protonged Healthcare Professional Area EU-EC- 11011092749 Resching - Caused/Protonged Healthcare Professional Area Not Resching - Caused/Protonged Healthcare Resching - Not R		28/12/2021	Spontaneous		European Economic				Female	No	Diplopia (n/a - Recovering/Resolving - Caused/Prolonged	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011092492 28/12/2021 Spontaneous Non Healthcare European Area Not 12-17 Not Recovered/Not R											(n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10011092749 EU-EC-											spectrum disorder (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10011092492 28/12/2021 Spontaneous Non Healthcare Professional EU-EC- 10011092749 28/12/2021 Spontaneous Healthcare Professional Recommic Area Professional European Recommic Area Recommendation Recommic Area Recommendation Recommic Resolving - Caused/Prolonged Hospitalisation) EU-EC- 10011092492 28/12/2021 Spontaneous Non Healthcare Professional Recommic Resolved -), EU-EC- 10011092749 28/12/2021 Spontaneous Healthcare Professional Recommic Recommi											Nystagmus (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10011092492 EU-EC- 10011092494 EU-EC-											Recovering/Resolving - Caused/Prolonged			
Healthcare Professional Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -) Polymenorrhoea (n/a - Not Recovered/Not Resolved											disorder (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10011092749 EU-EC- 10011092749 EU-FC- 10011092749 European Professional European Professional Economic Area Not Pemale No Angioedema (n/a - Unknown -) Angioedema (n/a - 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])		28/12/2021	Spontaneous	Healthcare	Economic				Female	No	(n/a - Not Recovered/Not	(S - Immunisation - n/a - [n/a	Not reported	<u>ICSR</u>
EU-EC- 10011092749 28/12/2021 Spontaneous Healthcare Professional Resolucian Professional Area Not Recovered/Not Resolved - Not Resolved - Not Angioedema (n/a - Unknown -) Unknown -) Angioedema (n/a - Unknown -) 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])											(n/a - Not Recovered/Not			
EU-EC- 10011092749 28/12/2021 Spontaneous Healthcare Professional Fender Reconomic Area Not reported Professional Reconomic Area Not reported Professional Fender Reconomic Area Not applicable - [n/a - n/a]											- Not Recovered/Not			
		28/12/2021	Spontaneous		Economic			Child	Female	No	Angioedema (n/a -	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
	EU-EC-	28/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Eyelid oedema (n/a -		Not reported	ICSR

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10011092803			Professional	Economic Area	available	Years				Recovering/Resolving - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Uveitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Visual impairment (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011093155	28/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011093200	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Child	Female	No	Chills (1h - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -)			
EU-EC- 10011093647	28/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										C-reactive protein increased (n/a - Not Recovered/Not Resolved -),			
										Chills (n/a - Not Recovered/Not Resolved -),			
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Ear pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -),			
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011094131	28/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011094470	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011094812	28/12/2021	Spontaneous		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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011095003	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness neurosensory (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Condition)			

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EU-EC- 10011095029	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011095046	28/12/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										- Other Medically Important Condition), Troponin I abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011095050	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
										Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oral pain (n/a - Recovering/Resolving -),			
										Respiration abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011095081	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lower respiratory tract infection (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011095089	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Asthenopia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Hepatitis (n/a - Recovering/Resolving - Other Medically Important			

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										Condition), Inflammation (n/a - Recovering/Resolving - Other Medically Important Condition), Liver function test abnormal (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
										Pericardial effusion (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011095103	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Unknown - Other Medically Important Condition)			
EU-EC- 10011095104	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Clonic convulsion (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Confusional state (n/a - Recovering/Resolving -),			
										Visual impairment (n/a - Recovering/Resolving			
EU-EC- 10011095156	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved -)			
EU-EC- 10011095159	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
				Area						Syncope (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10011095165	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011095167	28/12/2021	Spontaneous		Non 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 - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011095169	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011095170	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chromaturia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Glomerulonephritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Haematuria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Red blood cells urine positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Urinary occult blood positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-	28/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Dizziness (1h -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10011095172			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Headache (1h - Recovered/Resolved -), Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011095173	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011095176	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011095177	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (118h - Recovered/Resolved - Caused/Prolonged - Caused/Prolonged - Caused/Prolonged - Caused/Prolonged - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hospitalisation, Other Medically Important Condition), Myoglobin blood increased (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin increased (118h - Recovered/Resolved			
EU-EC- 10011095178	28/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation) Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area		, sais	Speamea			-), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011095185	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	- Caused/Prolonged Hospitalisation) Dizziness (0d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011095187			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011095197	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011095198	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011095202	28/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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				Economic Area						Headache (n/a - Unknown -),	Not applicable - [n/a - n/a - n/a])		
										Nausea (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Visual impairment (n/a - Unknown -)			
EU-EC- 10011095210	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Pericarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011095219	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -),			
						10.17				Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			1.000
EU-EC- 10011095220	28/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Alanine aminotransferase increased (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Blood lactate dehydrogenase increased (n/a - Unknown -),			
										Blood potassium decreased (n/a - Unknown -),			
										Blood uric acid increased (n/a - Unknown -),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011095228	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (25min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011095232	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Oxygen saturation decreased (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011095298	28/12/2021	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011095327	28/12/2021	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011095332	28/12/2021	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011095388	28/12/2021	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 - 30ug - Intramuscular])	Not reported	ICSR
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011095512		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	1 27		ICSR
EU-EC- 10011095529	28/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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			Professional	Economic Area						Resolved - Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Mobility decreased (n/a - Unknown - Other Medically Important Condition),			
										Paraesthesia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 100110957	50 28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC- 100110957		Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -),			
										Diarrhoea (n/a - Not Recovered/Not Resolved -),			
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lethargy (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rash (n/a - Not Recovered/Not Resolved -),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved -)			
EU-EC- 100110958		Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Condition aggravated (n/a - Unknown - Other Medically Important Condition),			
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			

										c Listing Report			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Muscle fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Post viral fatigue syndrome (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011096204	28/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011096208	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Testicular pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011096364	28/12/2021	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])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011096391	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Thrombosis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011096418	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN] [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011096615	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
										Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Vaccination site pain (n/a - Fatal - Results in Death)			
EU-EC- 10011096637	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Chest discomfort (n/a - Recovering/Resolving -),			
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Inflammation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011096640	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other			

		I								Medically Important			
EU-EC- 10011096658	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSF
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Monoplegia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011096695	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011096738	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10011096988	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSI
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011097009	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Heart rate irregular (n/a - Not Recovered/Not Resolved -),			
										Infection (n/a - Not Recovered/Not Resolved -),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011097086	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF
										Hyperhidrosis (n/a - Not Recovered/Not Resolved -),	,		
										Pyrexia (n/a - Recovered/Resolved -),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tinnitus (n/a - Not Recovered/Not Resolved -),			
										Visual impairment (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10011097112		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Glomerulonephritis membranous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	Intramuscular])		ICSF
EU-EC- 10011097116	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
										Troponin increased (n/a - Recovering/Resolving -)			
EU-EC-	28/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Arthralgia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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				Area						- Other Medically Important Condition),	Not applicable - [1d - 1{DF} - Intramuscular])		
										Inflammation (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011097304	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011097380	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Psoriasis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICS</u>
EU-EC- 10011097419	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site erythema (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
EU-EC- 10011097423	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenitis (n/a - Not Recovered/Not Resolved -)		Not reported	ICS
U-EC- 0011097437	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Recovered/Resolved -),	i	Not reported	ICS
										Vaccination site papule (n/a - Recovering/Resolving -)	Intramuscular j)		
U-EC- 0011097502	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Skin exfoliation (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
U-EC- 0011097588	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Disorientation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Inappropriate affect (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Muscle rigidity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

					ı					Listing report			
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (30min - Recovered/Resolved			
										- Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011097731	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Female	No	Vaccination site urticaria (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011097755	28/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Female	No	Dyspnoea (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -		<u>ICSR</u>
										Face oedema (1d - Recovered/Resolved -),	Intramuscular])		
										Immunisation reaction (2d - Recovered/Resolved -),			
										Lethargy (3d - Recovered/Resolved -),			
										Malaise (3d - Recovered/Resolved -)			
EU-EC- 10011097817	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (13d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011097854	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011098756	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011098855	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diabetic ketoacidosis (n/a - Fatal - Results in Death, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Fatal - Results in Death),			
										Palpitations (n/a - Fatal - Results in Death),			
										Pyrexia (n/a - Recovered/Resolved -),			
EU-EC-	28/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Vaccination site pain (n/a - Unknown -) Ageusia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011098871			Professional	European Economic Area	available	Years	Specified			Unknown -), Anosmia (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown -),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -), Pyrexia (n/a -			
										Unknown - Caused/Prolonged Hospitalisation),			

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										Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011098878	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Electrocardiogram abnormal (n/a - Unknown -), Sinus bradycardia (n/a - Unknown -),			
										Troponin increased (n/a - Unknown -)			
EU-EC- 10011098895	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011098910	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011098917	20, 12, 2021	Sportaineous		European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Total Topol toda	10011
EU-EC- 10011099073	28/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Discomfort (0d - Recovered/Resolved - Other Medically Important Condition), Dizziness (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovered/Resolved -),			
										Fear (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypoxia (2h - Recovered/Resolved - Other Medically Important Condition),			
								Pour		Lethargy (n/a - Recovered/Resolved -)			

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