## Line Listing Report Time run: 30/11/2022 12:33:34

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10009606462	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10009606472	05/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male	No	Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606474	05/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009606475	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (1d - Recovered/Resolved - ), Arthralgia (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Dyspnoea (0d - Recovered/Resolved - ),			
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved - ),			
										Oropharyngeal pain (1d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved - )			
10009606477		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606482	05/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Unknown - ), Vomiting (n/a - Not			
										Recovered/Not Resolved - )			
EU-EC- 10009606490	05/08/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (4d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CYPROTERONE ACETATE, ETHINYLESTRADIOL] (C - Acne - n/a - [n/a - 1{DF} - n/a])	ICSR
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009606494	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (52d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606497	05/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (1d - Recovered/Resolved - ), Diarrhoea (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (3d - Recovered/Resolved - ),			
										"			

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										(7d - Recovered/Resolved - ),			
										Oropharyngeal pain (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - ),			
										Vaccination site pain (2d -			
										Recovered/Resolved - ),			
										Vaccination site pain (n/a - Unknown - )			
EU-EC- 10009606498	05/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} -		
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009606499	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU EC	05/00/2021	Caratana	11	F	Net	12.17	A d = 1 = = = = = +	Na-1-	NI-	Albana di ababa 16	Unknown - [n/a - 1{DF} - n/a])	Not you sate d	TCCD
EU-EC- 10009606502	05/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009606507	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area		12-17 Years	Adolescent	Male	No	Speech disorder (0d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Vomiting (0d - Recovered/Resolved - )	1{DF} - n/a])		
EU-EC- 10009606516	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	Not reported	ICSR
											not changed - [n/a - 1{DF} - n/a])		
EU-EC- 10009606772	05/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
EU-EC- 10009606914	05/08/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a -	- Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Recovering/Resolving - )			
EU-EC- 10009607176	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LORATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - Oral])	ICSR
										Menstrual disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009607536	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Application site burn (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Erythema (n/a - Not Recovered/Not Resolved - Other			

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										Medically Important Condition),			
										Pain in extremity (n/a - Unknown - ),			
										Peripheral swelling (n/a - Unknown - Other Medically Important Condition),			
										Skin discolouration (n/a - Unknown - ),			
										Urticaria (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site vesicles (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009583059	04/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10009585989	04/08/2021	Spontaneous		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),		Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009587035	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009587125	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Endocarditis (n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009587916	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable = [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009588191	04/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Lymph node pain (2d	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Recovered/Resolved - ), Lymphadenopathy (2d - Recovered/Resolved - )	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009588883	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (2d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Body temperature decreased (2d - Recovered/Resolved - Disabling),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Chills (2d - Recovered/Resolved - Disabling),			
										Dizziness (2d - Recovered/Resolved - Disabling),			
										Fatigue (2d - Recovered/Resolved - Disabling),			
										Headache (2d - Recovered/Resolved - Disabling),			

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											Malaise (2d - Recovered/Resolved - Disabling),			
											Myalgia (2d - Recovered/Resolved - Disabling),			
											Nausea (2d - Recovered/Resolved - Disabling),			
											Pain in extremity (2d			
											Recovered/Resolved			
	U-EC-	04/08/2021	Spontaneous		European	Not		Adolescent	Female	No	- Disabling) Feeling cold (n/a -	COVID-19 MRNA	Not reported	ICSR
	.0009589077			Healthcare Professional		available	Years				Recovering/Resolving	(NUCLEOSIDE MODIFIED)		
											Headache (n/a - Recovering/Resolving - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION		
											Myalgia (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not		
											Nausea (n/a - Recovering/Resolving - ),	applicable - [n/a - n/a - n/a])		
											Pyrexia (n/a - Recovering/Resolving - ),			
											Vomiting (n/a - Recovering/Resolving			
	EU-EC- .0009589082	04/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male		Application site pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn	Not reported	ICSR
											Back pain (n/a - Recovered/Resolved - ),	- [n/a - n/a - Intramuscular])		
											Headache (n/a - Recovered/Resolved - ),			
											Poor quality sleep			
											Recovered/Resolved			
											I <del>-</del> )			
	EU-EC- 10009589552	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available		Not Specified	Female	No	- ) Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving	[TOZINAMERAN] (S -	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
		04/08/2021	Spontaneous	Healthcare	Economic				Female		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
	.0009589552			Healthcare Professional	Economic Area	available	Years	Specified			Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
E			Spontaneous	Healthcare Professional	Economic Area		Years				Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Not Resolved - ), Nausea (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) Myocarditis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
E	.0009589552	04/08/2021		Healthcare Professional  Healthcare Professional	European Economic Area	available	12-17 Years	Specified	Male		Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - O), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)  Body temperature increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])  COMIRNATY [TOZINAMERAN] (S -		
E	EU-EC- .0009590020	04/08/2021	Spontaneous	Healthcare Professional  Healthcare Professional	European Economic Area	available  Not available	12-17 Years	Adolescent  Not	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Botal Caused/Prolonged Hospitalisation)  Body temperature increased (n/a - Unknown - ), Discoloured vomit (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])  COMIRNATY	Not reported	ICSR
E	EU-EC- .0009590020	04/08/2021	Spontaneous	Healthcare Professional  Healthcare Professional	European Economic Area	available  Not available	12-17 Years	Adolescent  Not	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Nyalgia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovering/Resolving - ), Body temperature increased (n/a - Unknown - ), Discoloured vomit (n/a - Unknown - ) Discoloured vomit (n/a - Unknown - ) Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL -	Not reported	ICSR
E	EU-EC- .0009590020	04/08/2021	Spontaneous	Healthcare Professional  Healthcare Professional	European Economic Area	available  Not available	12-17 Years	Adolescent  Not	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Laryngitis (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Discoloured (n/a - Unknown - ), Discoloured vomit (n/a - Unknown - ), Discoloured vomit (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL -	Not reported	ICSR

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										Unknown - ), Headache (n/a -			
		-								Unknown - )			1
EU-EC- 10009590207	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19	Not reported	<u>ICSR</u>
EU-EC- 10009590213	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009590220	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acute respiratory failure (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590227	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (1wk - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (1wk - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590228	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ventricular extrasystoles (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590284	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pancreatitis acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009590551	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Loss of consciousness (n/a - Recovered/Resolved - ), Visual impairment (n/a - Recovered/Resolved Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590553	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Eye pain (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{OF} - Intramuscular])	Not reported	ICSR
10009590555		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site reaction (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Nausea (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- 10009590595	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	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- 10009590606	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009590627	04/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (1d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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				Area						Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Rash (1d - Recovered/Resolved	COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10009590640	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009590655	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Vertigo (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009590756	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590757	04/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anosmia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009590811	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash macular (24h - Recovering/Resolving - ), Urticaria (24h - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009590876	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009592855	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swollen tongue (30min - Recovered/Resolved - ), Throat tightness (30min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009593054	04/08/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Muscle spasms (30min - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009594096	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Palpitations (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009594102	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[AZELAIC ACID] (C - Acne - n/a - [n/a - n/a - Cutaneous]),  [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE] (C - Inflammation - n/a - [n/a - n/a - Oral]),  [CLINDAMYCIN, ANHYDROUS BENZOYL PEROXIDE, CLINDAMYCIN, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - Cutaneous]),  [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),  [ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a - Oral]),	
EU-EC-	04/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Abdominal	COMIRNATY	[TETRACYCLINE HYDROCHLORIDE] (C - Acne - n/a - [n/a - n/a - Oral]) Not reported	ICSR
10009594141			Healthcare Professional	Economic Area	available	Years				lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
EU-EC- 10009594169	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>

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										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (n/a -	immunisation - Unknown - [n/a - 1{OF} - Intramuscular])		
										Unknown - Caused/Prolonged Hospitalisation), Syncope (30min -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Tremor (0d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009594180	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009594196		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Lymphadenopathy (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009594611	04/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[DIENOGEST, ETHINYLESTRADIOL, LACTOSE ANHYDROUS] (C - Oil acne - Dose not changed - [n/a - n/a - Oral])	<u>ICSR</u>
EU-EC- 10009594617	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10009568114	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Injection site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009568130	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009568251	03/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[AMOXICILLIN SODIUM, CLAVULANIC ACTD, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009568283		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009569926	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - ), Dysaesthesia (n/a - Recovering/Resolving - ), Hypoaesthesia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC- 10009570488	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Differential white blood cell count abnormal (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

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										Recovering/Resolving - Other Medically Important Condition),			
										Electrocardiogram abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009571034	03/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petit mal epilepsy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009571443	03/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009571447	03/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Abdominal pain (n/a - Unknown - Other Medically Important Condition), Nausea (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-	03/08/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Rash (n/a - Unknown - Other Medically Important Condition) Inappropriate	TOZINAMERAN	Not reported	ICSR
10009571543			Healthcare Professional	European Economic Area	available	Years	Specified			schedule of product administration (n/a - Unknown - ), Pancreatitis acute (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])		
EU-EC- 10009572844	03/08/2021	Spontaneous		I - ' .	Not available	1	Not Specified	Male	No	Myocarditis (9d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009573142	03/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC- 10009574867	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not	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
										Resolved - ),  Malaise (n/a - Not Recovered/Not Resolved - ),	- n/a])		
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009575876	03/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pruritus (n/a - Unknown - Other Medically Important Condition),			
										Swelling face (n/a - Unknown - Other Medically Important Condition)			

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EU-EC- 10009575976	03/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
				Alea						Hypersensitivity (n/a - Unknown - ),	applicable - [n/a - n/a - n/a])		
										Malaise (n/a - Unknown - ),			
										Pain (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Swelling face (n/a - Unknown - ),			
										Weight decreased (n/a - Unknown - )			
EU-EC- 10009576021	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009576209	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Anal incontinence (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [n/a - 1{DF} - Intramuscular])		
										Chills (n/a - Recovering/Resolving - ),			
										Diarrhoea (n/a - Recovering/Resolving - ),			
										Loss of consciousness (10s - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Respiratory rate increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009576927	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	ARANESP [DARBEPOETIN ALFA] (C - n/a - Unknown - [n/a - n/a - n/a]),	<u>ICSR</u>
										Caused/Prolonged Hospitalisation), Chills (n/a - Not	applicable - [n/a - n/a - n/a])	[DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - Unknown	
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		- [n/a - n/a - n/a]),  JAKAVI [RUXOLITINIB, RUXOLITINIB PHOSPHATE] (C -	
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		n/a - Unknown - [n/a - n/a - n/a]), PRIVIGEN [HUMAN NORMAL IMMUNOGLOBULIN] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										Fibrin D dimer increased (n/a - Not Recovered/Not Resolved -		[AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										Caused/Prolonged Hospitalisation), Malaise (n/a - Not		[AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										Recovered/Not Resolved - Caused/Prolonged		[CARBAMAZEPINE,  CARBAMAZEPINE (PH. EUR.)] (C -	

										Hospitalisation, Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Respiratory disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		n/a - Unknown - [n/a - n/a - n/a]),  [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]),  [CLOBAZAM] (C - n/a - Unknown - [n/a - n/a - n/a]),  [DIMETINDENE MALEATE] (C - n/a - Unknown - [n/a - n/a - n/a]),  [ITRACONAZOLE] (C - n/a - Unknown - [n/a - n/a - n/a]),  [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a - n/a - n/a]),  [NIFEDIPINE] (C - n/a - Unknown - [n/a - n/a - n/a]),  [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM, SESQUIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
EU-EC- 10009577458	03/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	attention (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[SULFAMETHOXAZOLE, TRIMETHOPRIM, TRIMETHOPRIM LACTATE, SULFAMETHOXAZOLE] (C - n/a - Unknown - [n/a - n/a - n/a]) Not reported	ICSR
										- ), Dizziness (0d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ),			
										Tachycardia (1d - Recovering/Resolving - )			
EU-EC- 10009577625	03/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Measles (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009577664	03/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved - ) Lung disorder (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19	Not reported	ICSR
EU-EC- 10009577800	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	03/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
10009577843										Malaise (1d -	[Intramuscular])		
10009577843										Malaise (1d - Recovered/Resolved - Other Medically Important Condition)	initianiuscular j)		

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										Vaccination site pain (n/a - Recovering/Resolving	immunisation - Not applicable - [1d - 1{DF} -		
										- ), Vertigo (n/a - Recovering/Resolving	ini amusculai j		
										Vomiting (n/a - Recovering/Resolving			
EU-EC- 10009578039	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (1d - Recovered/Resolved -), Bronchospasm (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	Not reported	ICS
	03/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Resolved - ) Herpes zoster (n/a -	1{DF} - Intramuscular]) COMIRNATY	Not reported	ICSI
.0009578081			Healthcare Professional	Economic Area	available	Years				- )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])		
U-EC- 0009578159	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving - ), Vaccination site pain	COMIRNATY	Not reported	ICSF
										(n/a - Recovering/Resolving - ),	1{DF} -		
										Visual impairment (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009578204	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash papular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSE
U-EC- 0009578205	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye pruritus (1d - Recovered/Resolved - ), Lip oedema (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
										Throat irritation (1d - Recovered/Resolved			
EU-EC- 10009578212	03/08/2021	Spontaneous		European Economic Area		12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovered/Resolved - ), Syncope (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported	ICSF
	03/08/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved - ) Hyperthermia (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
.0009578215			Professional	Economic Area	available	Years				Recovered/Resolved - ), Partial seizures (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -		
EU-EC- 10009579667	03/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Recovering/Resolving - Other Medically Important Condition)	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009581418	03/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gait disturbance (n/a - Unknown - ), Hypersensitivity (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Malaise (n/a - Unknown - ),	- n/a])		
										Pain (n/a - Unknown - ),			
										Systemic lupus erythematosus (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009581553	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSR
									1	LEGEOWAN - 1	Intramuscular])		1

											1{DF} - Intramuscular])		
EU-EC- 10009581601		Spontaneous	Professional		Not available  Not available	12-17 Years	Adolescent		No	Rash (n/a - Recovered/Not Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COMID-18 immunisation -	GARDASIL 9 [HUMAN PAPILLOMAVIRUS TYPE 31 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 33 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 52 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 58 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CE	
											immunisation - Unknown - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009581630		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Adolescent		No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009581660		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009558125	02/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>

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											Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
											Pallor (n/a - Recovered/Resolved - Other Medically Important Condition),			
E	J-EC-	02/09/2021	Chantanagus	Hooltheare	Non	Not	12-17	Not	Male	No	Shock (n/a - Recovered/Resolved - Other Medically Important Condition) Blood pressure	COMIRNATY	Not reported	ICSR
	0009558441	02/06/2021	Spontaneous	Professional	Non European Economic Area	available		Specified	Male		decreased (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSK
											Blood pressure fluctuation (n/a - Recovered/Resolved - ),	- n/a])		
											Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Nausea (n/a - Recovered/Resolved - ),			
FI	J-EC-	02/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Presyncope (n/a - Recovered/Resolved - ) Dyskinesia (n/a -	TOZINAMERAN	Not reported	ICSR
	0009558456	02/00/2021	·	Healthcare		available		Specified	remale	No	Unknown - ),  Muscle twitching (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	not reported	ICSK
											Tic (n/a - Recovering/Resolving - ),			
											Tourette's disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	J-EC- 0009558980	02/08/2021	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
											Concussion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Fall (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Gait disturbance (n/a			
											Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Impaired work ability (2d - Recovered/Resolved - ),			
											Impaired work ability (2d -			
											Recovered/Resolved - Other Medically Important Condition),			
h-44	ıs://dan.e		<i>l</i>	 	1100 -						Respiratory tract infection (n/a - Recovered/Resolved			13/62

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										- Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vertigo (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009559169	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (3h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10009559722	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin I increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009560682	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (15min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Syncope (1min - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009560688	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (2d - Recovered/Resolved - ), Pain in extremity (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	DASSELTA [DESLORATADINE] (C - n/a - n/a - [n/a - 1{DF} - n/a])	- ICSR
										Recovering/Resolving			
EU-EC- 10009560903	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009561011	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Syncope (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009562390	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)	1,1-1,		
EU-EC- 10009562722	02/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Head injury (n/a - Unknown - Caused/Prolonged Hospitalisation),	.,,«1)		
										Malaise (n/a - Unknown - ), Syncope (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10009563940	02/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Extrasystoles (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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				Area						- Other Medically Important Condition), Malaise (1d - Recovered/Resolved - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009563977	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	02/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	- ) Headache (n/a - Not	COMIRNATY	Not reported	ICSR
10009564322	,,		Healthcare Professional	Economic	available	Years				Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Pain in extremity (n/a - Not Recovered/Not Resolved - )	,		
EU-EC- 10009564350	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Spontaneous haematoma (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009565257	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Disabling),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Disabling),			
										Myalgia (n/a - Not Recovered/Not Resolved - Disabling),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10009565311	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Hyperparathyroidism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Superficial vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009566104	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - ), Vertigo (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009566733	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Muscular weakness (n/a - Recovering/Resolving - ), Nervous system disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - )			
EU-EC- 10009567134	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Pain in extremity (3d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			

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										Pyrexia (3d - Recovered/Resolved - ),			
										Vaccination site pain (3d - Recovered/Resolved - )			
EU-EC- 10009567339	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009567989	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pleurisy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009567990	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved - ), Swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009567999	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	[BIFONAZOLE, CLOTRIMAZOLE] (C - Fungal infection - n/a - [n/a - n/a - Vaginal]), [ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Contraception - n/a - [n/a - n/a - Oral]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Urticaria -	
												HYDROCHLORIDE] (C - Gricaria - n/a - [n/a - n/a - Oral]),  [HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),  [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - Constipation - n/a - [n/a - n/a - Oral]),	
												[MICONAZOLE NITRATE, HYDROCORTISONE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]), [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Inflammation -	
												n/a - [n/a - n/a - Oral]),  [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Pharyngitis - n/a - [n/a - n/a - Oral]),  [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - n/a -	
EU-EC- 10009568009	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (1d - Recovered/Resolved - ), Respiration abnormal (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Oral]) Not reported	ICSR
EU-EC- 10009568011	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										(n/a - Recovering/Resolving - )			
EU-EC- 10009568017	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568019	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568020	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis allergic (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESLORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]),  AVAMYS [FLUTICASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),  OPATANOL [OLOPATADINE,	ICSR

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												OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	
												RELVAR ELLIPTA [FLUTICASONE FUROATE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]),	
												[AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID] (C - Cystitis - n/a - [n/a - n/a - Oral]),	
												[AZELASTINE HYDROCHLORIDE, FLUTICASONE PROPIONATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),	
												[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	
												[POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]),	
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)]),  [TERBUTALINE SULFATE] (C -	
												Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	
EU-EC- 10009568024	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving - ), Palpitations (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Resolved - ),  Restlessness (n/a - Recovering/Resolving - )			
EU-EC- 10009568025	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568030	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	DESLORATADINE [DESLORATADINE] (C - Mite allergy - n/a - [n/a - n/a - n/a]), VACCINE UNSPECIFIED [NOT AVAILABLE] (C - Mite allergy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009568036	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568041	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568045	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Confusional state (13d - Recovered/Resolved - ), Disturbance in attention (13d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic])	ICSR
										Dyspnoea (13d - Recovered/Resolved - ), Fatigue (13d - Recovered/Resolved			
EU-EC- 10009568046	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1/DE1 - n/a])	Not reported	ICSR
EU-EC- 10009568055	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (0d - Recovered/Resolved - ), Presyncope (0d - Recovered/Resolved	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
										- ), Urinary incontinence	Intramuscular])		

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										(0d - Recovered/Resolved - ),			
										Vomiting (0d - Recovered/Resolved			
EU-EC- 10009568057	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash pruritic (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568058	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cardiac discomfort (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Presyncope (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Resolved - )	IQUF - n/a])  COMIRNATY  [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009568062	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oropharyngeal pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ETONOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]),  [IVERMECTIN] (C - n/a - n/a - [n/a - n/a - Oral]),  [METRONIDAZOLE, METRONIDAZOLE BENZOATE, METRONIDAZOLE BBP, METRONIDAZOLE BP, METRONIDAZOLE SODIUM] (C - Vaginal infection - n/a - [n/a - n/a - vaginal]),  [PERMETHRIN] (C - n/a - n/a - [n/a - n/a - Cutaneous]),  [SULFUR, SULFUR DIL. D6 AQUOS., SULFUR TRIT. D3] (C - n/a - n/a - [n/a - n/a])	ICSR
EU-EC- 10009568067	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009568069	02/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[IBUPROFEN] (C - Pain - n/a - [n/a - n/a - Oral]),  [MOMETASONE FUROATE, MOMETASONE FUROATE MONOHYDRATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),  [SUMATRIPTAN, SUMATRIPTAN SUCCINATE] (C - Migraine - n/a - [n/a - n/a - Nasal])	ICSR
EU-EC- 10009568316	02/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abnormal faeces (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009568330	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Generalised tonic- clonic seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009568735	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009568750	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009557245	01/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (1d - Recovered/Resolved - ), Chills (1d - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										Headache (1d - Recovered/Resolved - ),			
										Injection site pain (2d - Recovered/Resolved - ),			
										Malaise (1d - Recovered/Resolved - ),			
										Myalgia (1d - Recovered/Resolved - ),			
EU-EC-	01/09/2021	Spontaneous	Hoalthearo	European	Not	12-17	Not	Male	No	Nausea (1d - Recovered/Resolved - ) Dizziness (n/a -	COMIRNATY	Not reported	ICSR
10009557388	01/06/2021	Sportaneous		Economic Area	available	Years	Specified	Male	INO	Recovering/Resolving - ), Lymphadenopathy		Not reported	<u>103K</u>
										(n/a - Recovering/Resolving - ),	Intramuscular])		
										Nausea (n/a - Recovering/Resolving - ),			
EU-EC-	31/07/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Pyrexia (n/a - Recovering/Resolving - ) Lymphadenopathy	COMIRNATY	Not reported	ICSR
10009553136			Professional		available	Years	Specified			(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
											1{DF} - Intramuscular])		
EU-EC- 10009553391	31/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	<u>ICSR</u>
										Pyrexia (1d - Recovered/Resolved - )	[n/a - n/a - Intramuscular])		
EU-EC- 10009553552	31/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - ),	immunisation - n/a -	Not reported	ICSR
										Chills (n/a - Recovering/Resolving - ),	[n/a - n/a - Intramuscular])		
										Decreased appetite (n/a - Recovering/Resolving			
										- ), Nausea (n/a - Recovering/Resolving - ),			
										Pain in extremity (n/a - Recovering/Resolving -),			
										Vertigo (n/a - Recovering/Resolving  - )			
EU-EC- 10009553712	31/07/2021	Spontaneous		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	Not reported	<u>ICSR</u>
										Body temperature increased (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - Intramuscular])		
										Cough (n/a - Not Recovered/Not Resolved - ),			
										Diarrhoea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	31/07/2021	Spontaneous	Healthcaro	European	Not	12-17	Not	Female	No	Vomiting (n/a - Not Recovered/Not Resolved - ) Pericarditis (n/a -	COMIRNATY	Not reported	ICSR
10009553776	31/0//2021	Spontaneous	Professional		available	Years	Specified	remale	INU		[TOZINAMERAN] (S - COVID-19	not reported	ICSK
EU-EC-	31/07/2021	Spontaneous		European	Not	12-17	Not	Female	No	Back pain (3h -	Intramuscular]) COMIRNATY	Not reported	<u>ICSR</u>
10009555876			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Chills (1h -	[TOZINAMERAN] (S - COVID-19 immunisation - Not		

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										Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Recovering/Resolving			
										- ), Pain in extremity (3h			
										- Recovered/Resolved			
EU-EC- 10009539777	30/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis	Not reported	ICSR
										Chills (n/a - Recovered/Resolved - ),	- Not applicable - [n/a 3mL - Intramuscular])		
										Lymphadenopathy (n/a - Recovered/Resolved - ),			
										Malaise (n/a - Recovered/Resolved - ),			
										Myalgia (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10009540104	30/07/2021	Spontaneous		European Economic Area	Not available		Not Specified	Male	No	Fibrin D dimer increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
				Arca						- Caused/Prolonged Hospitalisation),	immunisation - n/a - [n/a3mL -		
										Headache (n/a - Recovering/Resolving - Caused/Prolonged	Intramuscular])		
										Hospitalisation), Pyrexia (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Spinal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009540748	30/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (17h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	<u>ICSR</u>
EU-EC-	30/07/2021	Spontaneous	Non	Non	Not	12-17		Female	No	Heavy menstrual	- n/a]) TOZINAMERAN	Not reported	ICSR
10009541407			Healthcare Professional	European Economic Area	available	Years	Specified			bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Inappropriate schedule of product administration (n/a - Unknown - ),			
										Menstrual disorder (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-	30/07/2021	Spontaneous	Healthcaro	European	Not	12-17	Adolescent	Male	No	Overdose (n/a - Unknown - ) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10009541567	30/07/2021	Sportaneous	Professional		available	Years	Adolescent	Male	NO	Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSK</u>
EU-EC- 10009542525	30/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pulmonary embolism (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				AICO						- Life Threatening, Caused/Prolonged Hospitalisation)	immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009542699	30/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
ELLEC	20/07/2021	Sporter	Non	Euro	Not	12.17	Adolas	Eores'-	Ne	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIDNIATY	Not reported	Icca
EU-EC- 10009544016	30/0//2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	remale	No	Fatigue (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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			Professional	Area						- ), Headache (n/a -	n/a - n/a - [1d - n/a - n/a])		
										Recovered/Resolved			
										Hyperaesthesia (n/a			
										Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved - ),			
										Pain of skin (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Skin burning sensation (n/a - Recovered/Resolved			
EU-EC- 10009544055	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - n/a - Oral])	ICSR
										- ), Rash papular (n/a - Recovering/Resolving	Intramuscular])		
EU-EC- 10009545528	30/07/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Gait disturbance (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10009545528				Area	avallable	rears				Resolved - Caused/Prolonged Hospitalisation)	Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009546212	30/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				7 11 50						Heavy menstrual	applicable - [n/a - n/a - Intramuscular])		
										bleeding (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Ovarian cyst (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Ovarian cyst ruptured (89h -			
										Recovered/Resolved With Sequelae - Other Medically Important Condition)			
EU-EC- 10009546361	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Unknown - ),	applicable - [n/a - .3mL - Intramuscular])		
EU EC	20/07/2024		11 10			12.17	N			Lymphadenopathy (n/a - Unknown - )	TOTALIAMEDAN	N	TOCD
EU-EC- 10009546614	30/07/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a		
EU-EC- 10009547436	30/07/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Purpura (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10003317130			Torcasional	Area	available	rears				- Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [1d - 1{DF} -		
EU-EC- 10009547546	30/07/2021	Spontaneous		European	Not	12-17 Years	Adolescent	Female	No	Guillain-Barre	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10009547546			Professional	Economic Area	available	Years				syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [1d - 1{DF} -		
EU-EC-	30/07/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Peroneal nerve palsy	Intramuscular]) COMIRNATY	Not reported	ICSR
10009548219	, .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Healthcare	Economic Area	available	Years			Ĺ	(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009550215	30/07/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Deafness (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Economic Area						Resolved - Disabling, Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Tinnitus (n/a - Not Recovered/Not Resolved - Disabling,			

										Other Medically Important Condition)			
EU-EC- 10009551471	30/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551472	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551482	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Pharyngeal swelling (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551483	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009551502	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551526	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lip swelling (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551527	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009551546	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009551691	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009551708	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009524440	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009524533	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atonic seizures (n/a - Not Recovered/Not Resolved - ), Presyncope (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009527058	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (33h - Recovered/Resolved - ), Sialoadenitis (5d - Recovered/Resolved - Other Medically Important Condition), Swelling face (3d - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	GUANFACINE [GUANFACINE] (C - Autism spectrum disorder - n/a - [n/a - n/a - Oral]),  [RISPERIDONE] (C - Autism spectrum disorder - n/a - [n/a - n/a - Oral])	ICSR

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EU-EC- 10009528132	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovered/Resolved - ), Generalised tonic- clonic seizure (1min - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID] (C - Hypovitaminosis - n/a - [3wk - n/a - n/a])	ICSR
EU-EC- 10009528413	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009528875	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009529794	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling abnormal (0d - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved		[ATOMOXETINE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 80mg - Oral]), [GUANFACINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1mg -	ICSR
										- ), Hypertension (0d - Recovered/Resolved		Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Seasonal allergy -	
										Tachycardia (0d - Recovered/Resolved		n/a - [n/a - 5mg - n/a])	
										Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009530161	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009530196	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovering/Resolving - Disabling), Headache (1d - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Injection site reaction (1d - Recovering/Resolving - Disabling),			
										Malaise (1d - Recovering/Resolving - Disabling),			
										Pyrexia (1d - Recovering/Resolving - Disabling),			
										Vertigo (1d - Recovering/Resolving - Disabling)			
EU-EC- 10009530384	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Tinea pedis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009530602	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral]),	<u>ICSR</u>
										Dizziness (n/a - Recovering/Resolving - ),		[OLANZAPINE] (C - n/a - n/a - [n/a - n/a - Oral]),	
										Dysarthria (n/a - Recovering/Resolving - ), Facial pain (n/a - Recovering/Resolving		[PROPRANOLOL HYDROCHLORIDE] (C - Migraine prophylaxis - n/a - [n/a - n/a - Oral])	
										Headache (n/a - Recovering/Resolving			
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										Hypoaesthesia (n/a - Recovering/Resolving - ),			
										Muscle tightness (n/a			
										Recovering/Resolving - ),			
										Pain (n/a - Recovering/Resolving - ),			
										Pain in extremity			
										(n/a - Recovering/Resolving - ),			
										Tremor (n/a - Recovering/Resolving - ),			
										Vaccination site hypoaesthesia (n/a - Recovering/Resolving - ),			
										Vaccination site pain			
										Recovering/Resolving			
EU-EC- 10009531200	29/07/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female		Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
										Headache (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Injection site pruritus (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nasopharyngitis (n/a - Not Recovered/Not Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10009531367	29/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Asymptomatic COVID-19 (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	- n/a])		
EU-EC- 10009531368	29/07/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a -	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Condition)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009531370	29/07/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
				Area						Hospitalisation),	immunisation - Not applicable - [n/a - n/a	[OXCARBAZEPINE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Disease recurrence (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])		
										Epilepsy (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Condition),			

										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Status epilepticus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10009531617	29/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Administration site pain (n/a - Recovering/Resolving		Not reported	ICSR
										- ), Axillary pain (n/a - Recovering/Resolving	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										- ), Chills (n/a -			
										Recovering/Resolving - ), Pyrexia (n/a -			
EU-EC-	29/07/2021	Spontaneous		European	Not		Adolescent	Female	No	Recovering/Resolving - ) Influenza like illness	COMIRNATY	Not reported	ICSR
10009531701				Economic Area	available	Years				(n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10009532007	29/07/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blindness (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	- Intramuscular])		
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Inflammation (n/a - Not Recovered/Not Resolved - ),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - )			
EU-EC- 10009532061	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009532886	29/07/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC- 10009532897	29/07/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a	- Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Economic Area			·			Recovered/Resolved - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Chest pain (228h - Recovered/Resolved - ),			
										Costochondritis (n/a			
										Recovered/Resolved			
										Dyspnoea (12d - Recovered/Resolved - ),			
										Painful respiration (12d -			

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										Recovered/Resolved - ), Palpitations (30min - Recovered/Resolved			
EU-EC- 10009533393	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving - Disabling),     Skin disorder (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009533656	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition),  Malaise (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009533683	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009533774	29/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hepatic cytolysis (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	[AMOXICILLIN, AMOXICILLIN SODIUM, AMOXICILLIN TRIHYDRATE] (C - Tonsillitis - n/a - [n/a - n/a - Oral]), [FENTICONAZOLE NITRATE] (C -	ICSR
										Herpes virus infection (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])	n/a - n/a - ), [FUSIDIC ACID] (C - n/a - n/a - )	
										Immune thrombocytopenia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009533909	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrooesophageal reflux disease (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009533925	29/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (2d - Recovered/Resolved - )	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009533930	29/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009534184	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Resolved - ),  Vomiting (n/a - Not Recovered/Not Resolved - )	and an assalar j		
EU-EC- 10009534260	29/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009534668	29/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Female	No	Fatigue (n/a - Unknown - ), Malaise (n/a - Recovered/Resolved	Intramuscular])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [n/a -	Not reported	ICSR
										- ), Myalgia (2d - Recovered/Resolved - ), Nausea (0d - Recovered/Resolved	1{DF} - n/a])		
EU-EC- 10009535350	29/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009535735	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Arthralgia (n/a - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				7.11.00						Dyspnoea (n/a - Recovered/Resolved - ),	applicable - [n/a - n/a - Intramuscular])		
										Fatigue (n/a - Recovered/Resolved - ),			
										Limb discomfort (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved			
										- Other Medically Important Condition),			
										Pyrexia (14h - Recovered/Resolved - ),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009535856	29/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009536089	29/07/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved - )	[n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S -		
EU-EC- 10009536962	29/07/2021	Spontaneous	Non Hea <b>l</b> thcare	Non European	Not available		Not Specified	Female	No	Cognitive disorder (n/a - Unknown - ),	Immunisation - n/a - [n/a - 2{DF} - n/a]) TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Economic Area			'			Facial paralysis (n/a - Unknown - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Fall (n/a - Unknown - ),			
										Hallucination (n/a - Unknown - Other Medically Important Condition),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	29/07/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Muscle twitching (n/a - Unknown - ) Arthralgia (n/a - Not	TOZINAMERAN	Not reported	ICSR
10009537272		Spo. rancous	Healthcare Professional		available	Years	Specified	. S.riuje		Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Lip swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	.,, 41)		
										Peripheral swelling (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation),			

										Listing report			
EU-EC- 10009537287	29/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - 30mg - n/a])	ICSR
										Paraesthesia (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009537970	29/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009538015		Spontaneous	Healthcare Professional		Not available  Not	12-17 Years	Adolescent	Female	No	Back pain (n/a - Recovering/Resolving - ), Dizziness (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Recovering/Resolving - ) Chills (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
10009501393			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Diarrhoea (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Nausea (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Tremor (3d - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009503180		Spontaneous	Healthcare Professional	Area	Not available	Years	Not Specified	Male	No	Urticaria (n/a - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009504091		Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Not Specified	Male	No	Vaccination site hypoaesthesia (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - )	immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009504482	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - ), Chills (1h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Listing Report	ı	ı	
										Cold sweat (1h - Recovered/Resolved - ),			
										Headache (9h - Recovered/Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pyrexia (9h - Recovered/Resolved - ),			
										Syncope (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10009505375	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSR
										Vasculitic rash (n/a - Recovering/Resolving - Caused/Prolonged	withdrawn - [1d - .3mL -		
EU-EC- 10009505598	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Dermatitis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
											immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10009505785	28/07/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Autoinflammatory disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Cardiovascular disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation,			

										Other Medically Important Condition)			
EU-EC- 10009506920	28/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Not Recovered/Not Resolved - ), Bronchitis (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Epistaxis (n/a - Not Recovered/Not Resolved - ), Epistaxis (n/a - Not Recovered/Not Resolved - ), Haematocrit decreased (n/a - Unknown - ), Haemaglobin decreased (n/a - Unknown - Other Medically Important Condition), Red blood cell count decreased (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CALUMINIUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE, SODIUM CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE, SODIUM CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROXIDE, SODIUM HYDROXIDE, SODIUM HYDROXIDE, SODIUM HYDROXIDE, SODIUM HYDROXIDE, CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE GEL, DRIED USP, SODIUM HYDROXIDE CARBONATE, ALGINIC ACID, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, SODIUM ALGINATE] (C - n/a - n/a - [n/a - n/a - n/a]),  [FEXOFENADINE HYDROCHORIDE] (C - n/a - n/a - [n/a - n/a]),	ICSR
										width increased (n/a - Unknown - )		[IBUPROFEN, IBUPROFEN LYSINE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009507287		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebral venous sinus thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation),  Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation),  Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),  Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation),  Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation),  Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]),  [ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009508180	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving - ), Epistaxis (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - )	DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC- 10009509703	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Autoimmune disorder (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009509830	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immune thrombocytopenia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009510055	28/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - ), Chills (1d - Recovered/Resolved - ), Disorientation (2d - Recovered/Resolved - ), Dizziness (2d - Recovered/Resolved - ), Dysarthria (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

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										Fatigue (1d - Recovered/Resolved - ),			
										Somnolence (1d - Recovered/Resolved			
EU-EC- 10009511425	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Migraine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[DESLORATADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSI
										Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009511530	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10009511550	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009511551	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009511556	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009511570	28/07/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovering/Resolving - )	COMIRNATY	Not reported	ICSF
EU-EC- 10009511722	28/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]),  [LAMOTRIGINE] (S - Depression - Drug withdrawn - [48d -	[FLUOXETINE HYDROCHLORIDE] (C - Depression - Dose not changed - [n/a - n/a - Oral])	ICSI
EU-EC- 10009511821	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Neuralgia (72h - Recovered/Resolved - )	n/a - Oral])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009511850	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovering/Resolving - ), Gastrointestinal disorder (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSI
										Myalgia (n/a - Recovering/Resolving			
EU-EC- 10009511858	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Pityriasis rosea (n/a - Recovering/Resolving - )		Not reported	ICS
EU-EC- 10009512247	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Haemorrhagic ovarian cyst (n/a -			

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										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009512267	28/07/2021	Spontaneous	Non Hea <b>l</b> thcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSF
10003312207			Professional	Economic Area	available	icars	Specifica			Headache (n/a - Unknown - ),	COVID-19 immunisation - Not applicable - [n/a - n/a		
										Immune thrombocytopenia	- Intramuscular])		
										(n/a - Recovering/Resolving			
										- Life Threatening, Caused/Prolonged Hospitalisation,			
										Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved			
EU-EC-	29/07/2021	Spontaneous	Non	Europoan	Not	12-17	Adolescent	Malo	No	- Other Medically Important Condition) Diarrhoea (n/a - Not	COMIRNATY	Not reported	ICSR
10009512619	26/07/2021	Spontaneous	Healthcare	European Economic Area	available	Years	Adolescent	Male	INO	Recovered/Not Resolved -	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
										Caused/Prolonged Hospitalisation),	[n/a - n/a - n/a])		
										Influenza like illness (n/a - Not Recovered/Not			
										Resolved - Caused/Prolonged			
										Hospitalisation), Renal pain (n/a - Not			
										Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation),  Vomiting (n/a - Not			
										Recovered/Not Resolved -			
EU EC	20/07/2024	Constant	NI	F	Niet	12.17	NI-E	F	NI-	Caused/Prolonged Hospitalisation)	COMIDNIAT!	Networked	Teep
EU-EC- 10009513694	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving  - ),	COVID-19	Not reported	ICSR
										Lymphadenopathy (n/a - Not	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not			
										Resolved - ), Nausea (1d -			
EU-EC-	28/07/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved - ) Headache (n/a -	COMIRNATY	Not reported	ICSR
10009514323	20/0//2021	эропшисовэ	Healthcare	Economic Area	available	Years	ridolescene	l laic		Unknown - ),	[TOZINAMERAN] (S - n/a - n/a - [n/a -	The reported	1001
										Hyperhidrosis (n/a - Unknown - ),	2{DF} - n/a])		
										Nausea (n/a - Unknown - ),			
EU-EC-	20/07/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	Vertigo (n/a - Unknown - ) Liver function test	COMIRNATY	Not reported	ICCD
10009515583	26/07/2021	Sportaneous	Healthcare	Economic Area	available	Years	Adolescent	remale	NO	abnormal (n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009516143	28/07/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Arthralgia (1h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						- ), Body temperature	COVID-19 immunisation - Not applicable - [n/a -		
										increased (n/a - Not Recovered/Not	1{DF} - n/a]),		
										Resolved - ),	[ETHINYLESTRADIOL, LEVONORGESTREL]		
										Chills (n/a - Recovering/Resolving - ),	not changed - [n/a -		
										Fatigue (n/a - Not Recovered/Not Resolved - ),	n/a - n/a])		
										Headache (n/a - Not Recovered/Not			
										Resolved - ),  Malaise (n/a -			
										Recovering/Resolving - ),			

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										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009519346	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009519687	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (74d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (74d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009520399	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009520582	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Recovered/Resolved -), Local reaction (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10009520962	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved -), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - ), Infectious mononucleosis (n/a -			
										Recovered/Resolved - ), Lymphopenia (n/a - Recovered/Resolved			
										- ), Thrombocytopenia (n/a - Recovered/Resolved			
										- Other Medically Important Condition)			
EU-EC- 10009521354	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (21d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009521520	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	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	ICSR
EU-EC- 10009522404	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (10d - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Hospitalisation),  Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10009522540	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation)  Disturbance in attention (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Paraesthesia (3d - Recovered/Resolved - )			
EU-EC- 10009522546		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Peripheral vascular disorder (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009522921	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
											COMIRNATY [TOZINAMERAN] (S -		

											Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10009523105	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10009523227	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (10d - Recovered/Resolved - ), Vision blurred (10d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009523351	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- )   Dizziness (0d -   Recovered/Resolved  - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
EU-EC- 10009523911	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (1d - Recovered/Resolved - )	[n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009525002	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (2d - Recovered/Resolved	[N/a 1/4 1/4] COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009525015	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009525067	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Peripheral vascular disorder (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009525132	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Orthostatic hypotension (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009488458	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009488753	27/07/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - ) Confusional state (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10009-88733				Area	avallable	rears	Specified			Recovered/Resolved - ), Visual impairment (n/a - Recovered/Resolved	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10009490093	27/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (11d - Recovered/Resolved - ), Paraesthesia (11d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009490148	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10009490328	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Unknown - [n/a - 1{DF} -	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC- 10009493140	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vertigo (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Abdominal pain upper (n/a - Recovering/Resolving		AVAMYS [FLUTICASONE FUROATE] (C - n/a - Unknown - ),	ICSR
										- ), Confusional state (n/a - Recovered/Resolved - ),	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - Unknown - ), [PHLEUM PRATENSE (225)] (C - n/a - Unknown - )	
										Dermatitis allergic (n/a - Recovering/Resolving - ),	applicable - [n/a - n/a - n/a])		
										Diarrhoea (n/a - Recovered/Resolved - ),			

										Swelling face (n/a -			
EU-EC- 10009493257	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving - ) Lymph node pain (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) ITOZINAMERANI (S -	Not reported	ICS
EU-EC- 10009494385	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ),  Malaise (n/a - Not Recovered/Not Resolved - )  Headache (0d - Recovered/Resolved - ),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICS
										Pain in extremity (2d - Recovered/Resolved - )	MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])		
EU-EC- 10009495948	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved - ), Lymph node pain (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Resolved - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10009496127	27/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved - ) Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]), [NORETHISTERONE] (C - Polycystic ovaries - n/a - [4d - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety -	ICS
										Condition),  Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  C-reactive protein increased (n/a - Unknown - Other		n/a - [n/a - n/a - n/a])	
										Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Disturbance in attention (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not			
										Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10009496129	27/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - Other Medically Important Condition) Herpes ophthalmic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE] (C - n/a - n/a - [n/a - n/a - n/a]),	IC
										Herpes zoster (n/a - Not Recovered/Not Resolved - )	.,,41)	[PAROXETINE, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, PAROXETINE HYDROCHLORIDE,	,

												ANHYDROUS] (C - n/a - n/a - [n,  - n/a - n/a])	/a
EU-EC- 10009497057	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (4d - Recovered/Resolved - Other Medically Important Condition), Nausea (4d - Recovered/Resolved - ), Vomiting (4d - Recovered/Resolved Recovered/Resolved - Recovered/Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	27/07/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	- ) Abdominal pain	COMIRNATY	Not reported	ICSR
10009497066			Healthcare Professional	Economic	available	Years				upper (2d - Recovered/Resolved - ), Hyperhidrosis (2d - Recovered/Resolved - ), Hyperventilation (2d - Recovered/Resolved - ), Immunisation reaction (2d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Recovered/Resolved - Other Medically Important Condition), Pallor (2d - Recovered/Resolved - ),			
										Swelling (2d - Recovered/Resolved			
EU-EC- 10009497141	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009497368	27/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (1h - Recovered/Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009497370	27/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Female	No	Headache (48h - Recovered/Resolved - ), Vomiting (48h - Recovered/Resolved	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC-	27/07/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	- ) Lymphadenopathy	Intramuscular]) COMIRNATY	Not reported	ICSR
10009497432			Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - ), Tongue oedema (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009497954	27/07/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009500197	27/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Condition aggravated (n/a - Not Recovered/Not Resolved - ),			
										Pruritus (n/a - Not Recovered/Not Resolved - Other			

										Medically Important Condition)			
EU-EC- 10009500299	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Menstruation delayed (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Mood swings (n/a - Not Recovered/Not Resolved - ),			
										(n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009501722	27/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a	Not reported	ICSR
EU-EC- 10009478872	26/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Disabling),	- Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[FLUCLOXACILLIN, FLUCLOXACILLIN SODIUM, FLUCLOXACILLIN SODIUM MONOHYDRATE] (C - n/a - n/a - [15d - n/a - n/a])	ICSR
										Heart rate increased (n/a - Not Recovered/Not Resolved - Disabling)	- n/a])		
EU-EC- 10009478893	26/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (9054min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (9054min - Recovered/Resolved - Other Medically Important Condition),	,		
										Heat illness (9054min - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (9054min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009482469	26/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	SLENYTO 5 MG PROLONGED- RELEASE TABLETS [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - n/a]),	ICSR
										Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation),	The arrascalar jy	[FLUOXETINE] (C - Depression - n/a - [n/a - n/a - n/a])	
										Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009484143	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009484173	26/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (2d - Recovered/Resolved - Other Medically Important Condition)	1{DF} -	Not reported	ICSR
EU-EC- 10009484190	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009484248	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	[Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]),	[FERROUS FUMARATE] (C - n/a - n/a - ), [FOLIC ACID] (C - n/a - n/a - )	ICSR
											[MESALAZINE] (S - Colitis - Drug withdrawn - [42d - 2g - Oral])		
EU-EC-	26/07/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Headache (n/a -	COMIRNATY	Not reported	ICSR

	F	Professional	Economic Area	available	Years				Unknown - ),	[TOZINAMERAN] (S - COVID-19		
									Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
07/2021 Spo						Child	Female		- Other Medically Important Condition) Motor dysfunction	COMIRNATY TTOZINAMERANI (S -	Not reported	ICSR
			Area	available	rears				Recovering/Resolving - Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Not	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
									Resolved - Caused/Prolonged Hospitalisation),			
									Recovered/Resolved - Caused/Prolonged Hospitalisation)			
07/2021 Spc		Professional			12-17 Years	Adolescent	Male		Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
07/2021 Spo		Healthcare	Economic		12-17 Years	Adolescent	Male		(n/a - Recovering/Resolving	immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
07/2021 Spo		Professional			12-17 Years	Adolescent	Female		Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
07/2021 Spo	+	Healthcare	Economic		12-17 Years	Adolescent	Male		Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL -	Not reported	ICSR
07/2021 Spo	+	Healthcare	Economic		12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
07/2021 Spc		Professional			12-17 Years	Adolescent	Female		Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
07/2021 Spo		Professional			12-17 Years	Adolescent	Male		Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
	F	Healthcare Professional	European Economic Area	available	Years	Specified	Male		(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
97/2021 Spc		Professional			12-17 Years	Adolescent	Male		Recovering/Resolving - Other Medically	CONCENTRATE FOR DISPERSION FOR	NOT reported	ICSR
07/2021 Spc		Professional					Male		Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
000	7/2021 Sp	7/2021 Spontaneous   7/2021 Sp	7/2021 Spontaneous Healthcare Professional  7/2021 Spontaneous Non Healthcare Professional  7/2021 Spontaneous Non Healthcare Professional  7/2021 Spontaneous Non Healthcare Professional  7/2021 Spontaneous Healthcare Professional	Professional Economic Area  7/2021 Spontaneous Healthcare Professional Economic Area  7/2021 Spontaneous Healthcare Professional Economic Area  7/2021 Spontaneous Non Healthcare Professional Economic Area  7/2021 Spontaneous Non Healthcare Professional Economic Area  7/2021 Spontaneous Non Healthcare Professional Economic Area  7/2021 Spontaneous Healthcare Professional Economic Area	Professional Economic Area available Area  Professional Economic Area  Not available Area  Professional Economic Area	Professional Economic Area   Available   Years	Professional European Not Area Professional Economic Area Professional Professional Professional Area Professional Professi	Professional   Conomic   Area   Area	Professional   Female   Professional   Profession		Southerwood   Mailborne   Succession   Suc	

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										Recovered/Resolved - Other Medically Important Condition),			
										Visual impairment (n/a - Recovered/Resolved -)			
EU-EC- 10009486821	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Sensation of foreign body (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009487281	26/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Periorbital swelling (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009487361	26/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Lethargy (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
			Professional	Area						Myocarditis (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Pain (n/a - Unknown - ), Pyrexia (n/a -			
EU-EC-	25/07/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Unknown - ) Chills (n/a -	COMIRNATY	  [LEVOCETIRIZINE	ICSR
10009475965			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - n/a - n/a -	
										Headache (n/a - Recovered/Resolved - ),	applicable - [1d - 30ug - Intramuscular])	[n/a - 5mg - Oral])	
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10009476559	25/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (6h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009476575	25/07/2021	Spontaneous			Not available		Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovering/Resolving - ), Malaise (n/a -			
										Recovering/Resolving - )			
EU-EC- 10009476595	25/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009476694	25/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving - )	applicable - [n/a -		
EU-EC- 10009476749	25/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Chills (2h - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Nausea (1d - Recovered/Resolved - )			
EU-EC- 10009476853	25/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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										Injection site pain (4d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
J-EC- 0009476869	25/07/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Injection site pain (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving - )			
J-EC- 0009477042	25/07/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (3d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
J-EC- 0009477047	25/07/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Headache (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Injection site inflammation (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Injection site swelling (n/a - Not Recovered/Not Resolved - )			
J-EC- 0009477119	25/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disorientation (n/a - Unknown - ), Memory impairment	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
	25/25/2021					10.10				(n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
J-EC- 0009477279	25/0//2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	- ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Headache (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Hepatitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovering/Resolving - ),			
										Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pharyngitis (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			

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										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009477324	25/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved - ), Malaise (2h - Recovered/Resolved - ),			
										Nausea (n/a - Recovering/Resolving			
EU-EC- 10009477327	25/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009477400	25/07/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	- ) Chills (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10003 177 100				Area	available	rears	Specifica			- ), Fatigue (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a -		
										Headache (n/a - Recovering/Resolving - )			
EU-EC- 10009477503	25/07/2021	Spontaneous		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
EU-EC- 10009477566	25/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Injection site pain (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving - )			
EU-EC- 10009477617	25/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										- ), Headache (n/a - Recovering/Resolving - ),			
										Injection site inflammation (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Recovering/Resolving - ),			
										Injection site warmth (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (1d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Pyrexia (1d - Recovered/Resolved - )			
EU-EC- 10009472684	24/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Skin discolouration (n/a - Recovering/Resolving -)	immunisation - n/a - [n/a3mL -	Not reported	ICSR
EU-EC-	24/07/2021	Spontaneous		European	Not	12-17 Years	Not	Male	No		Intramuscular]) COMIRNATY	Not reported	ICSF
10009472979			Healthcare Professional	Economic Area	available	Years	Specified			(n/a - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not		

		1	l		l	l				Listing Report	applicable - [n/a - n/a		ı
EU-EC-	24/07/2021	Spontaneous		European	Not	12-17	Not	Female	No	Myalgia (n/a -	- Intramuscular]) COMIRNATY	Not reported	ICSR
10009473020			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Nausea (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Recovered/Resolved - ),	.3mL - Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10009473022	24/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSE
										Pyrexia (n/a - Recovered/Resolved - )	applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10009459948	23/07/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				7.1.50						Injection site pain (n/a - Not Recovered/Not Resolved - )	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009460002	23/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis	Not reported	ICSR
										Chills (n/a - Recovered/Resolved - ),	- n/a - [n/a3mL - Intramuscular])		
										Lymphadenopathy (n/a - Recovered/Resolved - ),			
										Malaise (n/a - Recovered/Resolved - ),			
										Myalgia (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10009460346	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available		Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - ),	applicable - [n/a - .3mL - Intramuscular])		
										Malaise (n/a - Recovering/Resolving - ),			
EU EC	22/07/2024	Constant	Nan	Non	Nick	12.17	Note	F1-	N-	Pyrexia (n/a - Recovering/Resolving - )		IMPTUM DUPNIDATE	TOOD
EU-EC- 10009460756	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 54mg - n/a])	ICSR
										Dizziness (n/a - Recovered/Resolved - ),	applicable - [1d - n/a - n/a])		
										Fatigue (n/a - Recovered/Resolved - ),			
										Headache (n/a - Recovered/Resolved - ),			
										Myalgia (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009460757	23/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Headache (3d - Recovered/Resolved - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - 10mg - Oral])	ICSR
EU-EC-	23/07/2024	Spontaneous	Non	Non	Not	12 17	Not	Male	No	Pyrexia (48h - Unknown - ) Cerebral	-,	[PARACETAMOL] (C - n/a - n/a -	ICCD
10009462003	23/0//2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	male	No	haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Cerebral thrombosis (n/a -	- n/a])		

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										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Cerebrovascular accident (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009462871	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable [1d - n/a - Intramuscular])	Not reported	ICSR
										Hallucination (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Memory impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Mental disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
FILEG	22/07/2021		Non		Net	12.17	Adelessant	- Family	W	Psychotic disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMPANY		Icco
EU-EC- 10009463117	23/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	remaie	Yes	Intermenstrual bleeding (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3s - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009463541	23/07/2021	Spontaneous	Healthcare Professional			12-17 Years	Not Specified	Female	No	Blister (n/a - Recovering/Resolving - ), Erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Recovering/Resolving - ), Peripheral swelling (n/a - Recovering/Resolving	- n/a])		
EU-EC- 10009464743	23/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	[n/a - 1{DF} - n/a])		
										Rash (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Rash pruritic (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009464959	23/07/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			

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										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009464972	23/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Injection site pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (1d - Recovered/Resolved - ), Myalgia (n/a - Recovered/Resolved			
EU-EC- 10009467233	23/07/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	- ) Myalgia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						- ), Pain in extremity (n/a - Recovered/Resolved - ),	COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved - ),			
										Vaccination site swelling (n/a - Recovered/Resolved - )			
EU-EC- 10009467417	23/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	Anaphylactic reaction (2d - Recovered/Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Dyspnoea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Malaise (1d - Recovered/Resolved - ),			
										Vomiting (2d - Recovered/Resolved - )			
EU-EC- 10009467512	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009467515	23/07/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009467548	23/07/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adult	Female	No	Immunisation reaction (6d -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC-	22/07/2021	Spontaneous		Area European	Not	12-17	Adolescent	Famala	No	Recovered/Resolved - Other Medically Important Condition) Chest pain (1d -	n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	Icco
10009467729	23/07/2021	Sportaneous	Professional	Economic Area	available	Years	Adolescent	remale	No	Recovered/Resolved - ),  Dyspnoea (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL -	Not reported	ICSR
										- ), Influenza like illness	Intramuscular])		
										(4d - Recovered/Resolved - ),			
										Urticaria (1d - Recovered/Resolved - )			
EU-EC- 10009469294	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),	- n/a])		
	22/67/5					10.1=				Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	20.470		
EU-EC- 10009469405	23/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged	COVID-19 - n/a - [n/a - n/a - n/a])		

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										Hospitalisation),  Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC-	23/07/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Chest pain (n/a -	TOZINAMERAN	Not reported	ICSR
10009469883	25/0//2021	Spontaneous			available		Specified			Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	The reported	2001
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU EO	20/07/2024					10.17				Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			1000
EU-EC- 10009470394	23/07/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ), Myalgia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug -	Not reported	<u>ICSR</u>
EU-EC- 10009447386	22/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Chills (n/a - Not Recovered/Not Resolved - ),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ),  Myalgia (n/a - Not Recovered/Not			
										Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009447405	22/07/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Malaise (1d - Recovered/Resolved - ), Myalgia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovering/Resolving - ),	1{DF} - n/a])		

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										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009447407	22/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
EU-EC-	22/07/2021	Casabarasas	Lias Mhasana	Non	Niet	12.17	Not	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	TOZINAMEDANI	CANNADIDIO FCANNADIDIO 1/C	ICCD
10009448835	22/07/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Specified	Маје	INO	Disease recurrence (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	CANNABIDIOL [CANNABIDIOL] (C - Epilepsy - n/a - [n/a - n/a - n/a]),  [CLOBAZAM] (C - Epilepsy - n/a -	ICSK
										Epilepsy (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- n/a])	[n/a - n/a - n/a]),  [PHENOBARBITAL,  PHENOBARBITAL SODIUM] (C - Epilepsy - n/a - [n/a - n/a - n/a])	
										Febrile infection- related epilepsy syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation),		Lhitehsà - 11/4 - 11/4 - 11/4 - 11/4])	
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009449846	22/07/2021	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 - n/a - n/a - [1d - n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Mental disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009449868	22/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	22/07/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Not Resolved - ) Urticaria (n/a - Not	COMIRNATY	Not reported	ICSR
10009450299 EU-EC-	22/07/2021	Chantanaous	Healthcare Professional		available Not	Years	Adolescent	Eomala	No	Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
10009450423	22/07/2021	Spontaneous	Healthcare	European Economic Area	available	Years	Adolescent	remale	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSK
										General physical health deterioration (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nasopharyngitis (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	22/07/2021	Spontaneous		European	Not	12-17	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - ) Rash papular (n/a -	COMIRNATY	[CLOBAZAM] (C - Epilepsy - n/a -	ICSR
10009450442			Healthcare Professional	Economic Area	available	Years				Vaccination site	[TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[n/a - n/a - Oral]),  [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - Oral]),	
EU-EC-	22/07/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Recovering/Resolving - ) Asthma (n/a -	TOZINAMERAN	[TOPIRAMATE] (C - Epilepsy - n/a - [n/a - n/a - Oral]) Not reported	ICSR
10009450613	. ,====		Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	·	
										Pyrexia (4d -	,,,,,,		

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009450718	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Basedow's disease (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Tachycardia (n/a - Unknown - )	- n/a])		
EU-EC- 10009450770	22/07/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Administration site pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Economic Area						- Life Threatening),	immunisation - Not applicable - [n/a -		
										Myocarditis (n/a - Recovering/Resolving - Life Threatening),	1{DF} - n/a])		
										Pain in jaw (n/a - Recovering/Resolving - Life Threatening)			
EU-EC- 10009451395	22/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Concussion (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Fall (n/a - Unknown - Caused/Prolonged Hospitalisation),	- n/a])		
										Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Unknown - ),			
										Muscle twitching (n/a - Unknown - ),			
										Nystagmus (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - ),			
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Unknown - )			
EU-EC- 10009451460	22/07/2021	Spontaneous		European Economic Area		12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),	[n/a - 1{DF} - Intramuscular])		
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009451632	22/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[LORATADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009451772	22/07/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Fatigue (n/a - Unknown - ),	COVID-19 immunisation - Not applicable - [1d - n/a		
										Generalised tonic- clonic seizure (n/a -	- Intramuscular])		
										Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - ),			
										Inflammation (n/a - Unknown - ),			
										Loss of consciousness (n/a -			
										Unknown - Other Medically Important Condition),			
										Oedema (n/a - Unknown - ),			
										STIMILOTVII ),			

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										Pain (n/a - Unknown - ), Seizure (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a -			
EU-EC- 10009452487	22/07/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COVID-19	Not reported	ICSR
				Area						Cough (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Dyspnoea (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 - ),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009452516	22/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ),	applicable - [1d - 30ug - Intramuscular])		
EU-EC-	22/07/2021	Spontaneous	Non	European	Not	12.17	Not	Mala	No	Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY	Not vanautod	TCCD
10009454090	22/07/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Vasodilatation (n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009454539	22/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Burning sensation (342h - Recovered/Resolved - Disabling), Burning sensation (78h - Recovered/Resolved - Disabling)	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009454574	22/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tremor (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]),	Not reported	ICSR
											[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE] (S - Urinary tract infection - Drug withdrawn - [5d - n/a - Oral])		
EU-EC- 10009454793	22/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hepatic cytolysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S -	[MELATONIN] (C - n/a - Not applicable - [n/a - 1mg - Oral])	ICSR
											NOVORAPID [INSULIN ASPART] (S - Type 1 diabetes mellitus - Drug withdrawn - [9d - n/a - Subcutaneous]),		
											TRESIBA [INSULIN DEGLUDEC] (S - Type 1 diabetes mellitus - Drug withdrawn - [9d - n/a - Subcutaneous])		
EU-EC- 10009454995	22/07/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Eye movement disorder (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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				Area						Recovered/Not Resolved - )	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009455481	22/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	PROTOPIC [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Topical]), [(HEXADECYL, OCTADECYL)-2-ETHYL HEXANOATE-ISOPROPYL MYRISTATE (6:3:1), LIQUID PARAFEIN, DODECYL-OMEGA-HYDROXYPOLY (DAYETHYLENE)-2, ALPHA (DODECYL, TETRADECYL)-OMEGA-HYDROXYPOLY (DAYETHYLENE)-5, ESTERS OF UNSATURATED FATTY ACIDS, LIQUID PARAFEIN, UNSATURATED FATTY ACIDS (C18:2)] (C - n/a - n/a - [n/a - n/a - Topical]), [ADAPALENE] (C - n/a - n/a - [n/a - n/a - Topical]), [LIPIDS NOS, UREA, UREA] (C - n/a - n/a - [n/a - n/a - Topical])	
EU-EC- 10009456054	22/07/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSI
				Area						Dizziness (n/a - Unknown - ), Pallor (n/a -	immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Unknown - ), Seizure like phenomena (n/a - Unknown - Other Medically Important			
EU-EC- 10009457031	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Generalised tonic- clonic seizure (2min - Recovered/Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	[CLOBAZAM] (C - Epilepsy - n/a - [n/a - n/a - n/a]),  [CLOBAZAM] (C - n/a - n/a - [n/a - n/a - n/a]),	ICS
										Condition),  Inappropriate schedule of product administration (n/a - Unknown - )	- Intramuscular])	[CYPROHEPTADINE HYDROCHLORIDE] (C - Appetite disorder - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - Epilepsy -	
										,		n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - Epilepsy - n/a	
EU-EC- 10009457508	22/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	- [n/a - n/a - n/a]) Not reported	ICS
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009458418	22/07/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Condition aggravated (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICS
										Epilepsy (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009458958	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a		ICS
										Chills (n/a - Recovering/Resolving - ),	- Intramuscular])	Contraception, Heavy menstrual bleeding, Menstruation irregular - n/a - [n/a - n/a - Oral])	
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Gait disturbance (n/a - Not Recovered/Not Resolved - Other			

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										Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Vision blurred (n/a - Not Recovered/Not			
										Resolved - Other Medically Important Condition)			
EU-EC- 10009459390	22/07/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Asthenia (0d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S -	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depressed	ICSR
				Economic Area						- ), Asthenia (n/a -	COVID-19 immunisation - Not applicable - [n/a - n/a	mood - n/a - [n/a - 25mg - Oral])	
										Unknown - ),	- n/a])		
										Blood pressure decreased (n/a - Recovered/Resolved - ),			
										Dizziness (n/a - Unknown - ),			
										Fatigue (0d - Recovered/Resolved - ),			
										Fatigue (n/a - Unknown - ),			
										Feeling abnormal (n/a - Recovered/Resolved -),			
										Hyperhidrosis (0d - Recovered/Resolved - ),			
										Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Musculoskeletal stiffness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (0d - Recovered/Resolved - ),			
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Speech disorder (0d			
										Recovered/Resolved - Other Medically Important Condition),			
										Staring (0d - Recovered/Resolved - Other Medically			
EU-EC- 10009431221	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available		Not Specified	Male	No	Important Condition) Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
EU-EC-	21/07/2021	Spontaneous	Hoalthcare	European	Not	12-17	Not	Female	No	Erythema (4d -	[n/a - n/a - Intramuscular]) COMIRNATY	Not reported	ICSR
10009431258	21/07/2021	Sportaneous	Professional	Economic Area	available	Years	Specified	remaie		Recovered/Resolved	[TOZINAMERAN] (S - COVID-19	Not reported	10010
										Periorbital oedema (4d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10009434038	21/07/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Erythema (n/a - Unknown - ),	COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
										Localised oedema (n/a - Unknown - ),	maanusculdi ])		
										Urticaria (n/a - Unknown - )			
EU-EC- 10009434102	21/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
										Pericarditis (n/a - Recovering/Resolving - ),	- n/a])		
										Pyrexia (n/a -			

		I	I	I	I	I	I	I		Recovering/Resolving	I	I	ı
		-								-)			
EU-EC- 10009434257	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Polyarthritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009434429	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICS
EU-EC- 10009435386	21/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 10mg - n/a])	ICSF
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- Intramuscular J		
EU-EC-	21/07/2021	Sportonogue	Non	Non	Not	12.17	Not	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMEDANI	FLAMOTRICINE / C. Frilgrey	ICCI
10009435439	21/0//2021	Spontaneous	Healthcare Professional	Non European Economic Area	available	12-17 Years	Specified	Male	No	Epilepsy (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a]),	ICSF
										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition),	- n/a])	[TOPIRAMATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	
										Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009436023	21/07/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
			Professional	Economic Area						Dizziness (n/a - Unknown - ), Fall (n/a - Unknown -	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										), Feeling abnormal (n/a - Unknown - ),			
										Headache (n/a - Unknown - ),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - ),			
										Nausea (0d - Recovered/Resolved - ),			
										Vision blurred (n/a -			
EU-EC- 10009437361	21/07/2021	Spontaneous	Healthcare	Non European Economic	Not available		Not Specified	Male	No	Unknown - ) Cold sweat (n/a - Recovering/Resolving - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Disorientation (2d - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Illness (n/a - Recovering/Resolving - ),			
										Lethargy (2d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (2d - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10009437459	21/07/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male		Arthralgia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[ALGELDRATE, TICK-BORNE ENCEPHALITIS VIRUS (INACTIVATED), NEUDOERFL	ICSR

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										Pyrexia (n/a - Recovered/Resolved - )	immunisation - Not applicable - [1d - 30ug - Intramuscular])	STRAIN, TICK-BORNE ENCEPHALITIS VIRUS] (C - n/a - n/a - [n/a5mL - Subcutaneous])	
EU-EC- 10009438641	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009439134	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	- n/a])		
EU-EC- 10009439755	21/07/2021	Spontaneous	Healthcare	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	Not reported	ICSF
										Fatigue (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
EU EC	21/07/2021	Constant	N	Nam	DI-t-	12.17	Net	FI-	N-	Myalgia (n/a - Not Recovered/Not Resolved - )	TOZINIAMEDANI	Network	Toon
EU-EC- 10009439927	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes ophthalmic (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009440578	21/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthritis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009441114	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009441315	21/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (3d - Recovered/Resolved -), Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										(3d - Recovered/Resolved - )	Intramuscular])		
EU-EC- 10009441386	21/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10009441433	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash pruritic (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	[LYMECYCLINE, TETRACYCLINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009442158	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	- n/a])		
EU-EC- 10009442214	21/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Adnexa uteri pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE	Not reported	ICSR
										Hot flush (n/a - Not Recovered/Not Resolved - ), Insomnia (n/a - Not Recovered/Not	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -		
EU-EC- 10009442338	21/07/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Resolved - )  Off label use (n/a - Unknown - ),	Unknown - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Underdose (n/a - Unknown - ),	COVID-19 immunisation - Not applicable - [n/a - .2mL -		
										Vaccination site pain (n/a - Unknown - )	Intramuscular])		-

10009443089	OMIRNATY FOZINAMERAN] (S - OVID-19 nmunisation - n/a -	Not reported	<u>ICSR</u>
	n/a3mL - ntramuscular])		
	OZINAMERAN FOZINAMERAN] (S -	Not reported	ICSR
Economic CO Area Eye disorder (n/a - imr Not Recovered/Not app	OVID-19 nmunisation - Not pplicable - [n/a - n/a Intramuscular])		
Fatigue (n/a - Unknown - ),			
Flushing (n/a - Unknown - ),			
Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
Status migrainosus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
Vestibular disorder (n/a - Not Recovered/Not Resolved - )			
EU-EC- 21/07/2021 Spontaneous Healthcare 10009443871 European Professional Economic available 12-17 Adolescent Female No Speech disorder (1d CO 100 100 100 100 100 100 100 100 100 10		AERIUS [DESLORATADINE] (C - n/a - n/a - ),	ICSR
- Caused/Prolonged imm Hospitalisation), app	OVID-19 nmunisation - Not pplicable - [n/a -	[FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE	
	{DF} - ntramuscular])	DIHYDRATE, FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR.] (C - n/a - n/a - ),	
		[SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a - )	
10009445591 Professional European Economic Area available Years Specified Unknown - Other Medically Important COndition) ITC Condition	OZINAMERAN  FOZINAMERAN] (S -  OVID-19  nmunisation - Not  pplicable - [n/a - n/a  n/a])	Not reported	ICSR
EU-EC- 20/07/2021 Spontaneous Healthcare European Not 12-17 Not Male No Sinus tachycardia CO	OMIRNATY	[PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - n/a]),	ICSR
Area Recovered/Resolved CO - Other Medically imm [Important Condition) [In/	OVID-19 nmunisation - n/a -	[SOTALOL, SOTALOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
10009411115   Professional   Economic   available   Years   Specified   (11d - Recovered/Resolved   CO   imr	OMIRNATY FOZINAMERAN] (S - OVID-19 nmunisation - Not pplicable - [n/a -	Not reported	ICSR
Lymphadenopathy 1{[	fpricable - [174 - {DF} - ntramuscular])		
10009413041   Professional   Economic   available   Years   Specified   Recovered/Not   TO CO	OMIRNATY FOZINAMERAN] (S - OVID-19	Not reported	ICSR
Pyrexia (n/a - Not app Recovered/Not .3n	nmunisation - Not pplicable - [n/a - BmL - ntramuscular])		
Urticaria (n/a - Not Recovered/Not Resolved - )			
10009413429   Professional   Economic   available   Years   Specified   Recovered/Resolved   TO   In/a	OMIRNATY FOZINAMERAN] (S - /a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 20/07/2021 Spontaneous Non European Not 12-17 Not Female No Nausea (n/a - CO 10009413733 Healthcare Economic available Years Specified No Nausea (n/a - Recovered/Resolved [TC]	Intramuscular]) OMIRNATY FOZINAMERAN] (S -	Not reported	ICSR
	OVID-19 nmunisation - n/a - n/a - n/a - n/a])		
Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10009413766 20/07/2021 Spontaneous Non Healthcare Professional Professional Real Professional Professional Real P	OMIRNATY FOZINAMERAN] (S - OVID-19 nmunisation - Not pplicable - [n/a - {DF} -	[DESOGESTREL] (C - Oral contraception - n/a - [n/a - n/a - Oral])	ICSR
	ntramuscular])	I	1

10009415155			Healthcare Professional		available	Years	Specified			Listing Report  Unknown - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a		
EU-EC- 10009415473	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved - ),	- n/a])  COMIRNATY  [TOZINAMERAN] (S - n/a - Not applicable -	Not reported	ICSF
										Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[n/a - 1{DF} - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009415474	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009415475	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009417156	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10009418077	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10009418092	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSI
EU-EC-	20/07/2021	Spontaneous	Haalthcare	European	Not	12-17	Not	Male	No	- Caused/Prolonged Hospitalisation) Dyspepsia (2d -	COMIRNATY	Not reported	ICSF
10009418388	20/07/2021	Spontaneous	Professional	Economic Area	available	Years	Specified	Male	No	Recovered/Resolved - ), Fatigue (2d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	not reported	1001
EU-EC- 10009420743	20/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSI
EU-EC- 10009421481	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (10min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
EU-EC- 10009422206	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Thrombocytopenia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSI
EU-EC- 10009422217	20/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blister (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSI
										Oral disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Skin lesion (n/a - Not Recovered/Not			

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										Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009422459	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422487	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422634	20/07/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), IgA nephropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19   immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009422643	20/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Seizure (n/a - Recovering/Resolving - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19] immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009422686	20/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422709	20/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422747	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422795	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009422933	20/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009423046	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009423047	20/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovering/Resolving - ), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a -	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009423664	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - )  Epistaxis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009423901	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009423957	20/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC-	20/07/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Tachycardia (n/a -	COMIRNATY	Not reported	ICSR

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10009425624			Professional	Economic Area	available	Years				Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
EU-EC- 10009425631	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009425633	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009426132	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009426229	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009426390	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypertensive crisis (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009426440	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009426514	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (0d - Recovered/Resolved - ), Headache (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009427549		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009427572	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Conjunctival oedema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009427573	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009427663	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009428886	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC- 10009429123	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Amnesia (0d - Recovered/Resolved - Other Medically Important Condition), Epilepsy (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009430486	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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MACCOND   September   Market											Recovered/Not			
2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-											Recovered/Not			
2407-2012   Spiriture   Spir											Recovered/Not			
March   Marc	EU-EC- 10009432087	20/07/2021	Spontaneous	Healthcare	Economic				Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a -	ICSI
20-000-000-000-000-000-000-000-000-000-											Recovering/Resolving Other Medically			
1967/2012   Sportstandous   Normal Healthcape   Surgiciary   Sportstandous   Normal Healthcape   Normal Heal	EU-EC- 10009432793	20/07/2021	Spontaneous	Healthcare	Economic				Male	No	Neck pain (n/a - Recovered/Resolved - ), Torticollis (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
Page	EU-EC- 10009400349	19/07/2021	Spontaneous	Healthcare	European Economic				Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]),	ICSR
											Recovering/Resolving - Other Medically Important	- Intramuscular])	CARBONATE] (C - Immunisation - n/a - [n/a - n/a - n/a]),  [FISH OIL] (C - n/a - n/a - [n/a -	
19/07/2021   19/07/2021   Sportaneous   Nor Healthcare   Compressional Professional   Area   Nor   Sportaneous   Nor   Sport											Loss of consciousness (n/a - Recovering/Resolving		[MONTELUKAST, MONTELUKAST SODIUM] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]),	
Peach Force   European Professional Forcessional Professional Profes	ELLEC	10/07/2021	Coontangous	Non	Non	Not	12.17	Not	Eomala	No		TOZINAMEDAN	[n/a - n/a - n/a])	ICCI
ELI-EC 19/07/2021 Sportaneous Non Non Registrate Professional Economic Area Non 10099403236 Professional Engages Professional Economic Area Non 1009940336 Professional Economic Non Non Professional Economic Non Non Registrate Professional Economic Non Non Non Non 1009940336 Professional Economic Non	10009400481	19/07/2021	Spontaneous	Healthcare	European Economic				remale	NO	Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
Healthrage   European Professional School											- Unknown - Other Medically Important	- Unknown])		
Specified   Spec	EU-EC- 10009400482	19/07/2021	Spontaneous	Healthcare	European Economic				Female	No	Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSF
Facial paralysis (n/a   Not reported   Not report	EU-EC- 10009402326	19/07/2021	Spontaneous	Healthcare	European Economic				Male	No	Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
Professional European   European   Area   Professional Economic   Area   Professional Economic   Area   Professional   Profe											Not Recovered/Not Resolved - Other Medically Important	1,74])		
Healthcare Professional Area Professional Area Professional I Prof	EU-EC- 10009403157	19/07/2021	Spontaneous		European Economic				Male	No	- Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (5 - Intramuscular])  ### Pyrexia (2d - Recovered/Resolved - ), ### Pyrexia (2d - Recovered/Resolved - )   ### Pyrexia (2d - Recovered/Res	EU-EC- 10009403383	19/07/2021	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Recovered/Resolved	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE	DIHYDROCHLORIDE] (C - n/a -	ICSR
EU-EC- 10009404782   Spontaneous   Healthcare   Foressional   Healthcare   Professional   Area   Spontaneous   Healthcare   Foressional   Healthcare   Professional   Healthcare   Professional   Healthcare   Professional   Healthcare   Heal											Recovered/Resolved	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S -		
Professional Economic Area  Professional Professional Economic Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Professional Economic Area  Professional Professional Economic Area  Professional Pr											Recovered/Resolved	applicable - [n/a - .3mL -		
Hypotension (n/a - Not Recovered/Not Resolved - Intramuscular])  Caused/Prolonged Hospitalisation, Other Medically Important Condition),	EU-EC- 10009404782	19/07/2021	Spontaneous		Economic			Adolescent	Male	No	- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important	19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S -	Not reported	ICSR
Rash (n/a - Not											Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important	applicable - [n/a - .3mL -		
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										Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 10009405813	19/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009405996	19/07/2021	Spontaneous	Non Healthcare Professional		Not available		Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Headache (6h - Recovered/Resolved - ), Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										(1d - Recovered/Resolved -), Malaise (1d -			
										Recovered/Resolved - ),  Pyrexia (6h - Recovered/Resolved - )			
EU-EC- 10009406000	19/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ), Body temperature increased (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ASCORBIC ACID, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [IBUPROFEN, IBUPROFEN D,L- LYSINATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Chills (8h - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - ),			
										Headache (7h - Recovered/Resolved - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving			
EU-EC- 10009407084	19/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not			
										Recovered/Not Resolved - ), Oropharyngeal pain			
										(n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not			
EU-EC-	19/07/2021	Spontaneous		European	Not	12-17	Not	Male	No	Recovered/Not Resolved - ) Malaise (n/a -	COMIRNATY	Not reported	ICSR
10009407730				Economic Area	available	Years	Specified			Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009407779	19/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009407801	19/07/2021	Spontaneous	Professional		Not available	12 <b>-</b> 17 Years	Not Specified	Male	No	Malaise (n/a - Recovered/Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										immunisation - Not		
										applicable - [n/a - 1{DF} -		
EU-EC- 10009407837	19/07/2021	Spontaneous	Economic	Not available	12-17 Years	Adolescent	Female	No	Asthenia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICS
									Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	[1d3mL - Intramuscular])		
									Headache (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
	10/07/2021				12.17				Tachycardia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMPANY		100
EU-EC- 10009408024	19/0//2021	Spontaneous	Economic	Not available	12-17 Years	Adult	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [n/a -	Not reported	ICS
									Chills (n/a - Recovering/Resolving - ),	1{DF} - n/a])		
									Dizziness (n/a - Not Recovered/Not Resolved - ),			
									Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
									Erythema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
									Fatigue (n/a - Not Recovered/Not Resolved - ),			
									Headache (n/a - Not Recovered/Not Resolved - ), Lip swelling (n/a -			
									Recovering/Resolving - Caused/Prolonged Hospitalisation),			
									Malaise (n/a - Not Recovered/Not Resolved - ), Mouth swelling (n/a -			
									Recovering/Resolving - Caused/Prolonged Hospitalisation),			
									Nausea (n/a - Recovering/Resolving - ), Pharyngeal swelling			
									(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009408085	19/07/2021	Spontaneous	Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICS
										immunisation - Not applicable - [n/a - 1{DF} - n/a])	PROBIOTICA [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]),  VOEDINGSSUPPLEMENT [NOT AVAILABLE] (C - n/a - n/a - [n/a -	
									Dysgeusia (n/a - Not Recovered/Not Resolved - ),		n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]),	
									Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a -		[ZINC SULPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
									Recovering/Resolving - ), Malaise (n/a -			
									Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving			
									- ),			
									Pyrexia (1d - Recovered/Resolved - )			

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										- ), Vomiting (2d - Recovered/Resolved	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009408236	19/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
FIL FO	10/07/2021	Constant	11-14	F	Net	12.17	Adalasasa	Famala	N-	Resolved - )	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Networked	ICCD
EU-EC- 10009408274	19/0//2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (3d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL -	Not reported	ICSR
EU-EC-	19/07/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Malaise (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10009408389	25,0,,2021	Бропсанова		Economic Area	available	Years	, asiasasii			Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		2001
EU-EC-	19/07/2021	Spontaneous		European	Not	12-17	Child	Female	No	Spontaneous	COMIRNATY	Not reported	ICSR
10009408474			Professional	Economic Area	available	Years				haematoma (n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC-	19/07/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Urticaria (n/a -	COMIRNATY	Not reported	ICSR
10009408501			Professional	Economic Area	available	Years				Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])		
EU-EC-	19/07/2021	Spontaneous		European	Not	12-17	Not	Male	No	Agitation (n/a -	COMIRNATY	Not reported	ICSR
10009408673			Professional	Economic Area	available	Years	Specified			Unknown - ),  Condition aggravated (n/a - Unknown - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
										Insomnia (n/a - Unknown - ),	- n/a])		
										Psychotic disorder (n/a - Unknown - )			
EU-EC- 10009409717	19/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (3d - Recovered/Resolved - ),			
										Nausea (3d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10009410712	19/07/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown - ), Injury (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Unknown - ), Loss of consciousness (n/a -	applicable - [n/a - n/a - Intramuscular])		
										Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009411477	19/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiovascular disorder (30min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
											applicable - [1d - n/a - n/a])		
EU-EC- 10009411820	19/07/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - Intramuscular]),	NOT AVAILABLE (C - Bronchiolitis - Not applicable - [n/a - n/a - Oral]),  [CITALOPRAM] (C - Attention	ICSR
											[AMOXICILLIN, CLAVULANIC ACID] (S - Urinary tract infection - Not	deficit hyperactivity disorder - Not applicable - [n/a - n/a - Oral]), [DESLORATADINE] (C - Dermatitis - Not applicable - [n/a - n/a -	
											applicable - [n/a - n/a - Oral])		
EU-EC- 10009412119	19/07/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Hodgkin's disease stage II (n/a -	TOZINAMERAN [TOZINAMERAN] (S -	Other]) AZATHIOPRINE [AZATHIOPRINE] (C - Transplant - n/a - [n/a - n/a -	ICSR
				Economic Area						Unknown - Caused/Prolonged	COVID-19 immunisation - Not	Oral]),	

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										Hospitalisation),	applicable - [n/a - n/a - Intramuscular])	[CICLOSPORIN] (C - Transplant -  n/a - [n/a - n/a - Oral]),	
										Insomnia (n/a - Unknown - ),	Traditioscularly	[PREDNISONE] (C - n/a - n/a -	
										Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		[n/a - n/a - n/a])	
										Lymphoproliferative disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Officer Medically Important Condition),			
										Post transplant lymphoproliferative disorder (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 1000941234		Spontaneous			Not available		Not Specified	Female	No	Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Injection site erythema (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Injection site swelling (n/a - Not Recovered/Not Resolved - ),			
										Injection site warmth (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (1h - Recovered/Resolved - )			
EU-EC- 1000939943		Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Chills (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Not			
										Recovered/Not Resolved - ), Malaise (n/a -			
										Recovering/Resolving - ), Myalgia (n/a - Not			
										Recovered/Not Resolved - ), Nausea (n/a - Not			
EU-EC- 1000939953		Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ) Body temperature increased (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Area						Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Resolved - ),			
										Injection site haematoma (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not			

										Recovered/Not Resolved - )			
EU-EC- 10009399543		Spontaneous	Healthcare Professional		Not	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ),  Injection site inflammation (n/a - Not Recovered/Not Resolved - ),  Injection site pain (n/a - Not Recovered/Not Resolved - ),  Injection site warmth (n/a - Not Recovered/Not Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSE
EU-EC- 10009399583		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009399602		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009392682	17/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009392690		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved - ), Pain in extremity (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009392691	17/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved - ), Pain in extremity (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009394383	17/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nausea (4h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF

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