## **Line Listing Report** Time run: 30/11/2022 11:22:32

EU Local Number	EV Gateway Receipt Date		Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Sex	Parent Child Report	- 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- 10010235094	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Disabling), Cold sweat (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Resolved - Disabling), Costochondritis (n/a - Not Recovered/Not Resolved - Disabling),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling),			
										Headache (n/a - Not Recovered/Not Resolved - Disabling),			
										Injection site pain (n/a - Not Recovered/Not Resolved - Disabling),			
										Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling),			
										Pallor (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Disabling),			
										Rash (n/a - Recovered/Resolved			
EU-EC- 10010235366	06/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	- ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Not Recovered/Not Resolved - ), Injection site pain	applicable - [n/a - 1{DF} - n/a])		
										(n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not			
EU-EC-	06/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Recovered/Not Resolved - ) Eczema (n/a - Not	COMIRNATY	Not reported	ICSR
10010235379	00,10,2021	Sportariesus	Healthcare Professional	Economic		Years	Specified			Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]),		1001
											[NOT AVAILABLE] (S - Skin disorder - Unknown - [2mo - n/a - n/a]),		
											[NOT AVAILABLE] (S - Wound infection bacterial - Not applicable - [12d - 1{DF} - n/a])		
EU-EC- 10010235584	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (2min - Recovered/Resolved - ), Ear discomfort (2min	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved	.3mL - n/a - More in ICSR])		
EU-EC- 10010236077	06/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU 50	06/40/5					12 :-				- Unknown - )	applicable - [n/a - 1{DF} - n/a])		****
'	06/10/2021	Spontaneous			Not	12-17	Not	Female	No	Dysmenorrhoea (n/a	COMIRNATY	Not reported	ICSR 1/6

30.11.2022 1	2.04							Run i	_ine L	isting Report			
10010236115			Healthcare Professional	Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Menstruation delayed (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010236125	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - ) Abnormal loss of weight (n/a - Recovering/Resolving - ), Chills (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Recovering/Resolving - ), Diarrhoea (n/a - Recovering/Resolving - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Malaise (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- 10010236129	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - ) Chills (1d - Recovered/Resolved - ), Fatigue (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved - ), Lymphadenopathy (3d - Recovered/Resolved - ), Myalgia (3d - Recovered/Resolved	1{DF} - n/a])		
EU-EC- 10010236171	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Syncope (1min - Recovered/Resolved - Other Medically Important Condition), Tonic clonic movements (1min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010236429	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (7d - Recovered/Resolved - Disabling), Gait disturbance (7d - Recovered/Resolved - Disabling), Loss of personal independence in	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										daily activities (7d - Recovered/Resolved - Disabling), Myalgia (7d - Recovered/Resolved - Disabling), Pain (7d -			
EU-EC-	06/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovered/Resolved - Disabling)  ADAMTS13 activity	COMIRNATY	Not reported	ICSR
10010236495	10/2021	эропапеоиѕ	Professional	European Economic Area	available	Years	Specified	н еш <b>аје</b>	INU	decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	not reported	<u>ILOK</u>
										Coagulopathy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			

).11.2022 1	2.04							Run	Line L	isting Report			
										Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged			
EU-EC- 10010236748	06/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation)  Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S -	Not reported	ICSF
										Anaphylactic shock (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fall (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Radial pulse abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010236819	06/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10010236836	06/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important			
EU-EC-	06/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Condition)  Abdominal pain (n/a	COMIRNATY	Not reported	ICSF
10010236932			Healthcare Professional		available	Years	Specified			Recovering/Resolving -), Headache (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										- ), Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (0d - Recovered/Resolved - )			
EU-EC- 10010236952	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010237091	06/10/2021	Spontaneous	Non Healthcare Professional		Not available		Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010237097	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR

J.11.2022 I	2.04							T Cult I	-IIIE L	isting Report			
										(1d - Recovered/Resolved - )			
EU-EC- 10010237117	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving - ), Menstruation	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
										irregular (n/a - Recovering/Resolving - )		[VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010237131	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
EU-EC-	06/10/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Breast tenderness (n/a - Unknown - ) Diplopia (n/a - Not	Intramuscular]) COMIRNATY	Not reported	ICSF
10010237297	30,10,2021	Spontal result	Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Pericarditis (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
										Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])		
										Rash (n/a - Not Recovered/Not Resolved - ),			
										Troponin increased (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010237371	06/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])		
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010237432	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Exercise tolerance decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- n/a])		
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Heavy menstrual bleeding (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Visual impairment (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010237522	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)			

30.11.2022 1	2.04							Kulli	LIIIE L	isting Report			
EU-EC- 10010237774	06/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC- 10010237813	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Arthralgia (2d - Recovered/Resolved -),  Chills (1h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovered/Resolved - ), Tremor (1h - Recovered/Resolved - )			
EU-EC- 10010237828	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010238008	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving Resolving)	COMIRNATY	Not reported	ICSR
										- Caused/Prolonged Hospitalisation)			
EU-EC- 10010238266	06/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Anxiety (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Arthralgia (n/a - Not Recovered/Not Resolved - ),  Hallucination (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Panic attack (n/a - Not Recovered/Not Resolved - ),  Panic attack (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening),  Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Resolved - Life			
EU-EC- 10010238696	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Threatening)  Cardiovascular insufficiency (n/a - Recovered/Resolved - ),  Hyperhidrosis (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSI
										Recovered/Resolved - ),  Pruritus (n/a - Recovered/Resolved - ),			
										Rash (n/a - Recovered/Resolved -),			
										Urticaria (n/a - Recovered/Resolved - )			
EU-EC- 10010238870	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (4d - Recovered/Resolved -), Heavy menstrual bleeding (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Recovered/Resolved -), Menstruation delayed (3wk -	1(8)		
EU-EC-	06/10/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Eomalo	No	Recovered/Resolved - ) Dyspnoea (n/a - Not	COMIRNATY	[ETHINYLESTRADIOL,	ICCI
10010238973	06/10/2021	Spontaneous	Healthcare	Economic Area	available	Years	Adolescent	remaje	INO	Recovered/Not Resolved - ), Immunisation	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL -	LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010239021	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010239077	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vestibular disorder (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
EU-EC- 10010239160	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
										Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Dyspnoea exertional (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hypertension (n/a - Recovered/Resolved			
EU-EC- 10010239253	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
EU-EC-	06/10/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Condition) Abdominal pain (n/a	- n/a]) TOZINAMERAN	Not reported	ICSF
10010239368			Professional	European Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Diplopia (n/a - Unknown - Other Medically Important Condition),	· <del>·</del>		
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010239596	06/10/2021	Spontaneous	Non Hea <b>l</b> thcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Conjunctivitis allergic (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF

30.11.2022 1										isting report			
			Professional	Economic Area						Recovered/Not Resolved - ), Eye allergy (n/a - Not Recovered/Not	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Resolved - ),  Eye irritation (n/a - Not Recovered/Not Resolved - ),			
										Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Intraocular pressure increased (n/a - Not Recovered/Not Resolved - ),			
										Intraocular pressure increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Ocular hyperaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010239709	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1{DF} - Parenteral])	Not reported	ICSR
EU-EC- 10010239738	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010239744	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )		Not reported	ICSR
EU-EC- 10010239806	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010239843	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010239857	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (2d - Recovered/Resolved - ), Asthmatic crisis (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010239961	06/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),	- n/a])		
										Eye pain (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Hypersomnia (n/a - Unknown - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important Condition),			

J.11.2022 1										isting report			
										Sinus disorder (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010239983	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypotension (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10010239998		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Impetigo (n/a - Recovering/Resolving - )	COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010240005	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (2d - Recovered/Resolved With Sequelae - ), Respiratory disorder (2d - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010240076	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash maculo-papular (24h - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010240202	06/10/2021	Spontaneous	Non 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 applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010240212	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (1d - Recovered/Resolved - ), Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010240438	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (1d - Recovered/Resolved - ), Chills (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [10s - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	06/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Medically Important Condition) Urticaria (n/a - Not	COMIRNATY	Not reported	ICSR
10010240691			Healthcare Professional	Economic	available	Years	Specified			Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010240708	06/10/2021	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 - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

J.11.2022 I	12.04							Rull	LIIIE L	isting Report			
										Migraine (1d - Recovered/Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010240719	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010241074	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (37d - Recovered/Resolved - ), Fatigue (19d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
										Pyrexia (19d - Recovered/Resolved	Intramuscular])		
EU-EC- 10010241111	06/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Recovering/Resolving - ),  Menstruation delayed (n/a -	immunisation - Not applicable - [n/a -		
EU-EC-	06/10/2021	Spontaneous	Non	Furonean	Not	12-17	Adolescent	Female	No	Recovering/Resolving - ) Injection site pain	COMIRNATY	Not reported	ICSR
10010241151	06/10/2021	Sportaneous	Healthcare Professional	European Economic Area	available	Years	Adolescent	remale	INO	(3d - Recovered/Resolved - ),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
										Vaccination site reaction (3d - Recovered/Resolved - )			
EU-EC- 10010241272	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema multiforme (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	[ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10010241581	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010241583	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010241706	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Chi <b>l</b> d	Male	No	Nausea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved - )	applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010241927	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Headache (3d - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (3d - Recovered/Resolved - )			
EU-EC- 10010241932	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Malaise (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		

0.11.2022 1							1			isting report	1	1	
										Menstrual disorder (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (0d - Recovered/Resolved - ),			
										Nausea (n/a - Recovering/Resolving - )			
EU-EC- 10010241935	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a - n/a - n/a])	'a <u>ICSR</u>
										Dizziness (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	06/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Nausea (n/a - Not Recovered/Not Resolved - ) Haematoma (n/a -	COMIRNATY	Not reported	ICSR
10010241995	00,10,2021	Sportaineous	Professional	Economic Area	available	Years	Specified	remaje			[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	not reported	10011
EU-EC- 10010242139	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10010242155	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - )	2{DF} - n/a])  COMIRNATY  [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010242172	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Soft tissue inflammation (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010242176	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Neuritis (n/a - Recovered/Resolved - ),	۱۷۵۱		
										Performance status decreased (n/a - Recovered/Resolved - )			
EU-EC- 10010242179	06/10/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Epstein-Barr virus infection (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
EU EO	05/40/2024	Construction	No		No.	12.17	No.	Mala	N.	Somnolence (n/a - Not Recovered/Not Resolved - )	COMPNATA	No.	Toop
EU-EC- 10010242320	06/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Lymphadenopathy (18h - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (1d - Recovered/Resolved - ),			
										Pyrexia (3h - Recovered/Resolved - )			
EU-EC- 10010242328	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Dizziness (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Recovering/Resolving			

0.11.2022 1	2.04							Kuii i	-iiie L	isting Report			
										- ), Paraesthesia (n/a - Recovering/Resolving - ), Pyrexia (n/a -			
EU-EC-	06/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Recovering/Resolving - ) Arthralgia (n/a - Not	COMIRNATY	[RETINOL] (C - n/a - n/a -	ICSR
10010242344	00,10,2021	Sporteiricous	Healthcare Professional	Economic	available	Years	Specified	Tidle		Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	[n/a - n/a - n/a])	ICOIN
										Chills (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Dyspnoea (n/a - Recovering/Resolving - ),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Injection site erythema (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 (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Palpitations (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010242399	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tinnitus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	06/10/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Pericarditis (n/a -	applicable - [n/a - 1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10010243339			Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010243573	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	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- 10010243614	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Vaccination site irritation (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC- 10010243661	06/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Essential tremor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Dust allergy - n/a - [n/a - 180mg - Oral]),	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged	I{DF} - Intramuscular])	[MOMETASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a - 50ug - Nasal]),	
										Hospitalisation), Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged		[TERBUTALINE SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	
										Hospitalisation), Migraine (n/a - Not			

).11.2022 1	2.04							IXuII	LIIIE L	isting Report			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010243708	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (3d - Recovered/Resolved - ), Fatigue (5d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Hypersensitivity (4d - Recovered/Resolved - ), Nasopharyngitis (5d			
										Recovered/Resolved			
										Pain (5d - Recovered/Resolved - ),			
										Swelling (3d - Recovered/Resolved - )			
EU-EC- 10010243771	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010243849	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (5d - Recovered/Resolved - ), Dysphagia (5d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Recovered/Resolved - ), Headache (5d -	1{DF} - Intramuscular])		
										Recovered/Resolved - ), Lymphadenopathy			
										(5d - Recovered/Resolved -),			
										Pyrexia (5d - Recovered/Resolved - )			
EU-EC- 10010244237		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Herpes zoster (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10010244292	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema multiforme (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010215055	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010215199	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved With Sequelae - ), Vertigo (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSF
EU-EC-	05/10/2021	Spontaneous		European	Not	12-17	Not	Female	No	With Sequelae - ) Headache (3d -	Intramuscular]) COMIRNATY	Not reported	ICSF
10010215256			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010215257	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010215259	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010215510	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - ), Pain (n/a - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010215585	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematuria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSF

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EU-EC- 1.0010215681	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (2d - Recovered/Resolved - ), Pain in extremity (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSI
EU-EC- 10010215702	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (1d - Recovered/Resolved - ), Pain in extremity (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSI
EU-EC- 10010215730	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Diarrhoea (1d - Recovered/Resolved - ), Pain in extremity (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICS
EU-EC- 10010215759	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (0d - Recovered/Resolved - ), Pyrexia (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICS
EU-EC- 10010216597	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin I increased (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10010217094	05/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Erythema (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Hypersensitivity (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Laryngeal oedema (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Mouth swelling (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Paralysis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Paralysis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),  Tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	

										With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation),			
										Wheezing (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010217323	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug reaction with eosinophilia and systemic symptoms (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dysphoria (n/a - Unknown - Other Medically Important Condition), Feeling abnormal			
										(n/a - Unknown - ),  Nausea (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010217604	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically			
EU-EC- 10010217855		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S -	Not reported	ICSR
										Anaphylactic shock (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010217879		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010218314	05/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010218318		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Unknown - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Dizziness (n/a - Unknown - Life Threatening),	- n/a])		
										Feeling abnormal (n/a - Unknown - Life Threatening),			
										Nausea (n/a - Unknown - Life Threatening),			
										Pallor (n/a - Unknown - Life Threatening),			
										Presyncope (n/a - Unknown - Life Threatening)			

30.11.2022 1								· (air i		isting report			
EU-EC- 10010218324	05/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Chromatopsia (n/a - Unknown - ),			
										Diarrhoea (n/a - Unknown - ),			
										Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Heart rate increased (n/a - Unknown - ),			
										Migraine with aura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a - Unknown - ),			
										Vaccination site pain (n/a - Unknown - )			
EU-EC- 10010218362	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010218575	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010218737	05/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Amnesia (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Insomnia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010218752	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19	Not reported	ICSR
EU-EC- 10010219168	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Blood pressure decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- Intramuscular])		
										Feeling abnormal			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Radial pulse abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
FILE C	05/10/202	Charter	Hoght-	Nor	Not	12.47	Not	Mal-	Ne	Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINIAMEDAN	Net sanate d	Iccs
EU-EC- 10010219200	105/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

0.11.2022 1	2.04							IXuII	LIIIE L	isting Report			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Heart rate increased (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010219224	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diabetes mellitus inadequate control (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010219228	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Blood pressure decreased (10min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010219261	05/10/2021	Spontaneous	Non Hea <b>j</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional			, suits	Эрсанса			- ), Chest pain (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a - n/a		
										Fatigue (n/a - Recovering/Resolving - ), Myalgia (n/a -			
EU-EC- 10010219496	05/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving - ) Headache (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Area			·			Malaise (n/a - Not Recovered/Not Resolved - ),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Syncope (20min - Recovered/Resolved			
EU-EC- 10010219658	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- )  Dizziness (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010220140	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010220167	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acne (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

.11.2022 1	2.0							1 (dil	LIIIC L	isting Report			
										Pruritus (n/a - Not Recovered/Not Resolved - ),	Immunisation - n/a - [n/a - n/a - n/a])		
										Rash (n/a - Not Recovered/Not Resolved - )			
U-EC- 0010220319	05/10/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male	No	Hypersensitivity (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
U-EC- 0010220458	05/10/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
										Injection site pain (0d - Unknown - ),	[n/a - n/a - n/a])		
										Injection site swelling (0d - Unknown - ),			
11.50	05/40/2024	C	1114	F	Note	10.17	Note	FI-	N.	Vaccination site discomfort (0d - Unknown - )	COMPNIATIO	Not assessed	Tech
U-EC- 0010220517	05/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (2h - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Larynx irritation (2h - Recovered/Resolved - Other Medically Important Condition),			
										Lip swelling (2h - Recovered/Resolved - Other Medically Important Condition),			
										Paraesthesia oral (2h			
										Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0010220890	05/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]),	ICS
										Abdominal pain upper (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - n/a - Intramuscular])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 54mg - Oral])	
										Chest pain (n/a - Recovered/Resolved - ),			
										Cough (n/a - Recovered/Resolved - ),			
										Decreased appetite (n/a - Not Recovered/Not Resolved - ),			
										Dysphagia (n/a - Not Recovered/Not Resolved - ),			
										Dyspnoea (n/a - Recovered/Resolved - ),			
										Fatigue (n/a - Recovering/Resolving - ),			
										Fluid intake reduced (n/a - Recovering/Resolving			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Infectious mononucleosis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Lip swelling (n/a - Not Recovered/Not Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			

										to the state of th		1	
										Nasal congestion (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Pain (n/a - Not Recovered/Not			
										Resolved - ),  Pharyngeal disorder (n/a - Not			
										Recovered/Not Resolved - ), Pyrexia (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010221367	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010221440	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - ),	Intramuscular])		
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010221561	05/10/2021	Spontaneous		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	<u>ICSR</u>
										Headache (n/a - Recovered/Resolved - ),	applicable - [n/a - n/a - n/a])		
										Loss of personal independence in daily activities (2d - Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved - ),			
										Pain (n/a - Recovered/Resolved - ),			
										Pain in extremity (n/a - Recovered/Resolved			
										Vomiting (24h - Recovered/Resolved			
EU-EC- 10010221590	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Loss of personal independence in daily activities (2d - Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved - ),			
										Pain (n/a - Recovered/Resolved - ),			
										Pain in extremity (n/a - Recovered/Resolved -),			
EU SO	0E/10/2023	Cna-tr	Nor	Euros	Not	12.47	Not	Mala	N-	Vomiting (n/a - Recovered/Resolved - )	COMIDNATY	Not rope: 1	ICC
EU-EC- 10010221591	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Exercise tolerance decreased (24h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a -	applicable - [n/a - n/a - n/a])		

30.11.2022 1	2.04							Kuiri	-IIIE L	isting Report			
										Recovered/Resolved - ), Headache (n/a - Recovered/Resolved			
										Loss of personal independence in daily activities (2d -			
										Recovered/Resolved - ),  Musculoskeletal disorder (24h - Recovered/Resolved			
										- ), Nausea (n/a - Recovered/Resolved - ),			
										Pain (n/a - Recovered/Resolved - ),			
										Pain in extremity (n/a - Recovered/Resolved -)			
EU-EC- 10010221708	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	<u>ICSR</u>
										Cough (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not	- n/a])		
										Recovered/Not Resolved - ), Ear pain (n/a - Not			
										Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not			
										Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not			
										Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	05/10/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Sensitive skin (n/a - Not Recovered/Not Resolved - ) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR
10010222004	03/10/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	remale		Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ностеропеа	ICSIN
EU-EC- 10010222197	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),  Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC-	05/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Angina pectoris (n/a	immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10010223192				Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010223474	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Exercise tolerance decreased (n/a - Not Recovered/Not			

).11.2022 1	2.04							IXuIII	-IIIe L	isting Report			
										Resolved - ), Restlessness (n/a -			
										Not Recovered/Not Resolved - ), Tachycardia (n/a -			
										Not Recovered/Not Resolved - )			
EU-EC- 10010223607	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Heavy menstrual bleeding (2d - Recovering/Resolving - )	[ , , , , , , , , , , , , , , , , , , ,		
EU-EC- 10010224045	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Muscle spasms (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Muscle twitching (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Restless legs syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	05/10/2021	Spontaneous	Haalthcara	Non	Not	12-17	Not	Female	No	Small fibre neuropathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Chills (n/a - Not	COMIRNATY	Not reported	ICSR
10010224171	05/10/2021	эропшисоцз	Professional	European Economic	available	Years	Specified	Ciriale		Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19	Not reported	ICON
				Area						Dizziness (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Haematemesis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010224277	05/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (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
										Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),	- iyajy		
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010224490	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a -	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved - ),	Intramuscular])		
										Nausea (n/a - Recovered/Resolved - ),			

1.11.2022 1	2.04							Ruii	LIIIE L	isting Report			
										Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010224591	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010224734	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Injection site erythema (n/a - Not Recovered/Not Resolved - ),	1{DF} - n/a])		
										Injection site swelling (n/a - Not Recovered/Not Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010224765	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Aphonia (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
EU-EC-	05/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Myalgia (n/a - Not Recovered/Not Resolved - ) Asthenia (n/a -	applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a -	ICSF
10010224804	03/10/2021	эропшисоиз	Healthcare Professional	Economic	available	Years	Specified	remaje		Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	n/a - [2d - n/a - n/a]),  [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL	ICSI
										Blindness transient (n/a - Recovered/Resolved - Other Medically Important	- n/a])	SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	
										Condition),  Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Neck pain (n/a - Unknown - Other Medically Important Condition),			
										Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010225008	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Autoimmune thyroiditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10010225055	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
EU-EC- 10010225070	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (33d - Recovering/Resolving - Other Medically Important Condition)		Not reported	ICSI
EU-EC-	05/10/2021	Spontaneous		European	Not	12-17 Voors	Adolescent	Male	No	Multisystem	1{DF} - Intramuscular])  COMIRNATY	Not reported	ICSI
10010225127			Professional	Economic Area	available	Years				inflammatory syndrome in children	[TOZINAMERAN] (S - COVID-19		

										(n/a - Recovering/Resolving - Life Threatening)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010225195	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	IC
										Tachycardia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010225813	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>IC</u>
EU-EC- 10010225817	05/10/2021	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	10
EU-EC- 10010225832	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cystitis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>I</u> C
EU-EC- 10010225838	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>I</u> (
EU-EC- 10010225860	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	Ī
U-EC- 0010225864	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	Ī
U-EC- 0010225888	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (2d - Recovered/Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Vomiting (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	
EU-EC- 10010225978	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	Ī
EU-EC- 10010225984	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	Ī
EU-EC- 10010225988	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (6d - Recovered/Resolved - ), Headache (6d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	1
										Heavy menstrual bleeding (6d - Recovered/Resolved -)			
:U-EC- .0010226056	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (2d - Recovered/Resolved - ), Chest pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular - More	Not reported	<u> </u>

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10010226063			Professional	Economic Area	available	Years				Unknown - ), Vertigo (15d - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -		
EU-EC- 10010226079	05/10/2021	Spontaneous	Non Healthcare Professional	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 - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010226682	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010226879	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010226892	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010226922	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (9d - Recovered/Resolved - ), Fatigue (8d - Recovered/Resolved - ), Influenza like illness (9d - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010227062	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Clonic convulsion (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010227218	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (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- 10010227387	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (5min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]	Not reported	ICSR
EU-EC- 10010227547	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),  Back pain (n/a - Not Recovered/Not Resolved - ),  Ear pain (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Swelling (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010227620	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10010227698	05/10/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
				Area						Lip oedema (n/a - Unknown - ), Pyrexia (n/a -	immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010227721	05/10/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Dizziness (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	n/a - n/a - [n/a - n/a - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010227757	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010227770	05/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (1wk - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										- ), Asthenia (1wk - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Dysstasia (1wk - Recovered/Resolved - ),			
										Malaise (1wk - Recovered/Resolved - ),			
										Pyrexia (1wk - Recovered/Resolved - ),			
										Vomiting (1wk - Recovered/Resolved - )			
EU-EC- 10010227858	05/10/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood chloride decreased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Area						Blood potassium decreased (n/a - Unknown - ),	applicable - [1d - n/a - n/a])		
										Blood sodium decreased (n/a - Unknown - ),			
										Gamma- glutamyltransferase decreased (n/a - Unknown - ),			
										Granulocyte count decreased (n/a -			

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										Unknown - ), Lymphocyte count increased (n/a - Unknown - ),			
										Monocyte percentage increased (n/a - Unknown - ),			
										Neutrophil count decreased (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Pyrexia (6d - Recovered/Resolved - Life Threatening),			
										Vomiting (6d - Recovered/Resolved - ),			
										White blood cell count decreased (6d			
EU-EC- 100102281	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - Life Threatening) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Condition), Gingival swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Lip blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Oral herpes (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tongue blistering (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 100102287		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - ), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving - )			
EU-EC- 100102288		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (2d - Recovered/Resolved - ), Chills (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										- ), Fatigue (n/a - Not Recovered/Not	-(,) -(,)		
										Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),			
										Injection site inflammation (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Recovering/Resolving - ),			
										Injection site swelling (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a -			

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EU-EC- 10010228840	05/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	- ), Nausea (0d - Recovered/Resolved - ), Swelling face (n/a - Not Recovered/Not Resolved - ) Injection site pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Recovered/Resolved - ), Injection site paraesthesia (n/a - Recovered/Resolved - ), Muscle twitching (n/a - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - )	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010229017	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Infection - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10010229049	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10010229098	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Insomnia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010229099	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010229102	05/10/2021	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	Not reported	ICSR
EU-EC- 10010229109	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010229168	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (Od - Recovered/Resolved - Other Medically Important Condition), Syncope (Od - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010229248	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010229258		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	immunisation - Not applicable - [1d - 1{DF} - n/a - More in ICSR])	Not reported	ICSR
EU-EC- 10010229285	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Fema <b>l</b> e	No	Breast pain (n/a - Recovering/Resolving - ),  Menstrual disorder (n/a - Recovering/Resolving - ),  Migraine (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010229294	05/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Painful respiration (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	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,	ICSR

1	I	I	I	I	I	I	I	1	1	- Caused/Prolonged	I	HIIMAN PAPTI I OMAV/TDI IS	I
										- Caused/Prolonged Hospitalisation)		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 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 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 16 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 16 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 CELLS (SACCHAR	
EU-EC- 1001020351		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
EU-EC- 1001020383		Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (0d - Recovered/Resolved - Other Medically Important Condition), Deafness (0d - Recovered/Resolved - Other Medically Important Condition),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Heart rate increased (0d - Recovered/Resolved -), Mydriasis (0d - Recovered/Resolved -),			
										Presyncope (0d - Recovered/Resolved			
EU-EC- 1001020416		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncope (n/a - Unknown - Other Medically Important Condition), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown - Other Medically Important Condition)			
EU-EC- 1001020426		Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

	2.04							· · ·	C L	isting Report			
				Economic Area						Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Drug ineffective (n/a	.,,=3,		
										Recovering/Resolving - Other Medically Important Condition),			
										Menstruation delayed (n/a - Not Recovered/Not			
EU EC	04/10/2021	Caratana	N	Non	N-4	12.17	NI-4	CI-	NI-	Resolved - )	TOZINAMEDAN	Not and the d	ICCD
EU-EC- 10010204388	04/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	04/10/2021	Spontaneous		European	Not	12-17	Not	Female	No	Heavy menstrual	COMIRNATY	[ETHINYLESTRADIOL,	ICSR
10010205061			Healthcare Professional	Economic Area	available	Years	Specified			bleeding (n/a - Not Recovered/Not Resolved - ), Menstrual disorder	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a]),  [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a -	
										(63d - Unknown - )		n/a - [n/a - n/a - n/a])	
EU-EC- 10010205137	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Blepharospasm (n/a - Unknown - )			
EU-EC- 10010205305	04/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea haemorrhagic (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
										Pain (n/a - Recovered/Resolved With Sequelae - ),			
										Pyrexia (n/a - Recovered/Resolved With Sequelae - ),			
EU 50	0.1/10/2021					10.17		-		Vomiting (n/a - Recovered/Resolved With Sequelae - )	COMPNET		1000
EU-EC- 10010205523	04/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	гетаје	No	Skin haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010205605	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation)  Chest pain (1h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Chills (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (2d - Recovered/Resolved - ),			
										Injection site pain (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Palpitations (1d - Recovered/Resolved - ),			
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - ) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR
10010205624	0 1/ 10/ 2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	, ciliale	140	Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19	not reported	1COK

											immunisation - Not		
											applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010205628	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (1d - Recovered/Resolved - ), Chills (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Fatigue (n/a - Recovering/Resolving - ),			
										Malaise (1d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
	04/10/2021	Coopten	Nam	F	Net	12.17	Nat	Mala	N-	Syncope (1d - Recovered/Resolved -)	COMIDNIATY	Net reported	Icc
EU-EC- 10010205642	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (4h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICS</u>
										Diarrhoea (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Hyperpyrexia (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Vomiting (n/a - Recovering/Resolving - ) Fatigue (1d -	COMIRNATY	Not reported	ICSI
10010205649	04) 10) 2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	Hale	NO	Recovered/Resolved - ), Headache (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	100
										- ),  Malaise (1d - Recovered/Resolved	1(DF) - Iyaj)		
										- ), Urticaria (n/a - Not Recovered/Not			
EU-EC- 10010205840	04/10/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Encephalopathy (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI
				Area						Recovered/Resolved - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])		
EU-EC- 10010206029	04/10/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICS
			TOICSSIONA	Area						- Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010206033	04/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
				, n Ca						Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10010206058	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Diarrhoea (n/a - Recovering/Resolving - ),	applicable - [n/a - n/a - Intramuscular])		
										"			

										Vaccination site pain (n/a - Recovering/Resolving			
EU-EC- 10010206070	04/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [1d -	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	.3mL - Intramuscular])		
										Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vertigo (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010206195	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscular weakness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved - ), Pain in extremity	1{DF} - n/a])		
EU-EC-	04/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	(2wk - Not Recovered/Not Resolved - ) Dizziness (n/a -	COMIRNATY	AVAMYS 27.5	ICSR
10010206225			Professional	Economic Area	available	Years	Specified			Recovering/Resolving - ),  Headache (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE]	
										Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a -		(C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-	04/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Recovering/Resolving - )  Myocarditis (3d - Not	COMIRNATY	Not reported	ICSF
10010206293	0 1/10/2021	Sportaneous	Professional	Economic Area	available	Years	Specified	Tidle .		Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	not reported	1001
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010206301	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010206375	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast enlargement (n/a - Recovering/Resolving -), Breast pain (n/a -	COMIRNATY CONCENTRATE FOR	Not reported	ICSF
										Recovering/Resolving - ),  Menstrual disorder (n/a - Unknown - )			
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Angina pectoris (3d -	COMIRNATY	Not reported	ICSR

0.11.2022 1	12.04							Rull	Line L	isting Report			
10010206481				Economic Area	available	Years				Recovered/Resolved - Disabling), Chest pain (3d - Recovered/Resolved - Disabling), Chills (2d - Recovered/Resolved - Disabling), Fatique (3d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
										Recovered/Resolved - Disabling),  Palpitations (3d - Recovered/Resolved			
										- Disabling)			<u> </u>
EU-EC- 10010206613	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010206641	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Monoparesis (n/a - Recovering/Resolving - ), Vaccination site nerve damage (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- ), Vaccination site pain (n/a - Recovering/Resolving - )			
EU-EC- 10010206769		Spontaneous  Spontaneous	Healthcare Professional	European Economic Area	Not available Not	12-17 Years	Adolescent  Adolescent		No No	Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported  Not reported	ICSR
10010207082	04/10/2021	Spontaneous	Healthcare Professional	Economic Area	available	Years	Adolescent	Maic	INO	Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZIMAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSK
EU-EC- 10010207138		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Injection site erythema (2d - Recovered/Resolved - ), Injection site haematoma (2d - Recovered/Resolved - ), Injection site inflammation (2d - Recovered/Resolved - ), Injection site inflammation (2d - Recovered/Resolved - ), Injection site pain (2d - Recovered/Resolved - ), Malaise (3d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved - ) Myalgia (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported  Not reported	ICSR
10010207143			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010207148	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Heart rate increased (1min - Recovered/Resolved -), Malaise (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010207167		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown - ), Vaginal haemorrhage (n/a - Unknown - )	applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010207176		Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Lymphadenitis (6d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	[BECLOMETASONE DIPROPIONATE,	<u>ICSR</u>

			Professional	Area						-)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),  [MONTELUKAST, MONTELUKAST SODIUM] (C -	
EU-EC- 10010207184	04/10/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - n/a - [n/a - n/a - n/a])  Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Injection site erythema (2d - Recovered/Resolved - ),			
										Injection site inflammation (2d - Recovered/Resolved - ),			
										Injection site pain (2d - Recovered/Resolved -),			
										Injection site pruritus (2d - Recovered/Resolved -),			
										Injection site warmth (2d - Recovered/Resolved - ),			
										// Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
									Nausea (n/a - Recovering/Resolving - ),				
										Palpitations (n/a - Recovering/Resolving - )			
U-EC- 0010207211	04/10/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19	Not reported	<u>I</u> 0
										Breast tenderness (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Chills (n/a - Not Recovered/Not Resolved - ),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Injection site haematoma (n/a - Not Recovered/Not Resolved - ),			
										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 - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			

0.11.2022 1	2.04							Run I	_ine L	isting Report			
										Nausea (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not			
										Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Tremor (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010207218	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovering/Resolving - ),			
										Oropharyngeal pain (n/a - Recovering/Resolving -),			
										Sneezing (n/a - Recovering/Resolving - )			
EU-EC- 10010207258	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (3d - Recovered/Resolved - Disabling), Headache (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved - Disabling),	.3mL - Intramuscular])		
										Lymphadenopathy (5d - Recovered/Resolved - Disabling),			
										Pyrexia (3d - Recovered/Resolved - Disabling),			
										Vaccination site oedema (3d - Recovered/Resolved - Disabling)			
EU-EC- 10010207746	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	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- 10010208548	04/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tonic convulsion (n/a	TOZINAMERAN	[ALIMEMAZINE TARTRATE] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]),  [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]),	
										- Unknown - Other Medically Important Condition)		[SODIUM VALPROATE] (C - Generalised tonic-clonic seizure - n/a - [n/a - n/a - n/a])	
EU-EC- 10010208573	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscle spasms (7d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	<u>ICSR</u>
										Myalgia (7d - Recovered/Resolved - )	[n/a - n/a - n/a])		
EU-EC- 10010208587	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hodgkin's disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010208629	04/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Hospitalisation)  Cardiac arrest (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	n/a - n/a - [n/a - n/a - n/a])		
										Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010208680	04/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Nasal congestion	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - ),	Zira ani usculai ])		
										Rhinorrhoea (n/a -			

30.11.2022 1	2.04							Run	Line L	isting Report			
										Not Recovered/Not Resolved - ), Throat irritation (n/a			
										- Not Recovered/Not Resolved - ),			
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010208729	04/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Headache (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Recovering/Resolving - ),			
EU-EC-	04/10/2021	Spontaneous	Hoalthcaro	European	Not	12-17	Adolescent	Malo	No	Pyrexia (n/a - Not Recovered/Not Resolved - ) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10010208850	04/10/2021	Sportaneous		Economic Area	available	Years	Adolescent	male	INO	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSK</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010208853	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010209285	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
FILE C	04/10/2021	Consideration	New	F	Note	12.17	Net	FI-	N.	Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	-	Networked	Teep
EU-EC- 10010209289	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eczema (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Not Resolved - )	-		
EU-EC- 10010209293	04/10/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown - ), Polymenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	- Unknown - )  Heavy menstrual	COMIRNATY	Not reported	ICSR
10010209311		,	Healthcare Professional	Economic Area	available	Years	Specified			bleeding (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	, L	
EU-EC- 10010209313	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	AVAMYS 27.5 MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C	<u>ICSR</u>
										Myalgia (2d - Recovered/Resolved - ),	Intramuscular])	- Hypersensitivity - n/a - [n/a - 27.5ug - n/a])	
										Pyrexia (2d - Recovered/Resolved - ),			
										Vaccination site pain (3d - Recovered/Resolved -)			
EU-EC- 10010209322	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Heavy menstrual	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										bleeding (n/a - Recovering/Resolving - ),	Intramuscular])		
										Nausea (n/a - Unknown - ), Vomiting (n/a -			
EU-EC-	04/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Unknown - ) Alopecia (n/a -	COMIRNATY	[BIOTIN] (C - Alopecia - n/a -	ICSR
10010209567			Professional	Economic Area	available	Years				Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]),	[n/a - n/a - n/a])	
											KAFTRIO [TEZACAFTOR,		

0.11.2022 1	2.04							Run	Line L	isting Report			
											ELEXACAFTOR, IVACAFTOR] (S - Cystic fibrosis - Dose not changed - [n/a - 2{DF} - Oral]), KALYDECO		
EU 50	04/10/2021		li e libere e		N-1	12.17	Net	NA-I-		A the state ( ) (s	[IVACAFTOR] (S - Cystic fibrosis - Dose not changed - [n/a - 1{DF} - Oral])	No.	TOCO
EU-EC- 10010209834	04/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										- ), Diarrhoea (n/a - Recovering/Resolving - ),			
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -), Malaise (n/a -			
										Recovering/Resolving - ), Myalgia (n/a -			
										Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10010209905	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -		
										Menstrual disorder (8d - Recovered/Resolved -),	Unknown - [n/a - n/a - n/a])		
										Pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010209964	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Recovered/Resolved -)			
EU-EC- 10010210271	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010210325	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010210338	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hypertension (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
										Pericardial disease (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010210378	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

	2.04									Myocarditis (n/a - Recovering/Resolving			
	04/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	- Caused/Prolonged Hospitalisation)  Paraesthesia (n/a -	Intramuscular])  COMIRNATY	Not reported	ICS
10010210391			Healthcare Professional	Economic Area	available	Years				- ), Urticaria (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		
										Recovering/Resolving - Other Medically Important Condition)	1{DF} -   Intramuscular])		
EU-EC- 10010210460	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vascular purpura (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Not	Not reported	ICS
EU-EC- 10010210500	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010210509	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
EU-EC- 10010210574	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICS
5U.50	04/40/2024					12.17		No. I.		Hospitalisation),  Influenza like illness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMPANY		100
EU-EC- 10010210601	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010210962	04/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (610min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICS
										Blood pressure decreased (585min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- Intramuscular])		
										Cold sweat (610min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (405min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate decreased (610min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypotension (585min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (610min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Presyncope (610min - Recovered/Resolved			
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	- Caused/Prolonged Hospitalisation) Herpes zoster (n/a -	COMIRNATY	Not reported	ICS
10010211185	,,	, , , , , , , , , , , , , , , , , , , ,	Healthcare Professional	Economic	available	Years	Specified			Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	,	
EU-EC-	04/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Syncope (1min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS

											.3mL - Intramuscular])		
EU-EC- 10010211277	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Affect lability (n/a - Recovering/Resolving - ), Heavy menstrual bleeding (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Malaise (n/a - Recovering/Resolving - ),			
										Menstruation delayed (4d - Recovering/Resolving -),			
										Premenstrual pain (n/a - Recovering/Resolving -)			
EU-EC- 10010211658	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site erythema (5d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Injection site inflammation (5d - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (5d - Recovered/Resolved -),			
										Injection site swelling (5d - Recovered/Resolved -),			
										Lymphadenopathy (6d - Recovered/Resolved -),			
										Myalgia (3d - Recovered/Resolved - )			
EU-EC- 10010211736		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menstruation delayed (n/a - Unknown - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10010211759	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oral mucosal blistering (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010211776	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010211805	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010211831	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (15d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010211843	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (3mo - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010211868	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Dyspnoea (4d - Recovering/Resolving -), Feeling drunk (2d -	applicable - [1d - 1{DF} - Intramuscular])		
										Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved			
EU-EC-	04/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	- ) Lymphadenopathy	COMIRNATY	Not reported	ICSI
10010211874	, 10, 2021		Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -		1001
EU-EC-	04/10/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Eyelid oedema (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSF

0.11.2022 1								· tuii i		isting report			
10010212054		·	Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -		
EU-EC- 10010212386	04/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - ), Depressed level of consciousness (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										- Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - ),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010212548	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Menstruation delayed (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved - )			
EU-EC- 10010212809	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	04/10/2021	Spontaneous		European	Not	12-17		Female	No	Headache (n/a - Not	COMIRNATY	Not reported	ICSR
10010213038			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Syncope (n/a - Recovering/Resolving - )			
EU-EC- 10010213055	04/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovering/Resolving - ), Injection site			
										inflammation (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Recovering/Resolving - ),			
										Injection site swelling (n/a - Recovering/Resolving - )			
EU-EC- 10010213291	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dizziness (8h - Recovered/Resolved - ), Fatigue (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ), Nausea (n/a -			
										Recovering/Resolving - ),  Pyrexia (n/a - Not			
										Recovered/Not Resolved - ),			
										Recovering/Resolving			
EU-EC- 10010213899	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - 6mg - n/a]), [LISDEXAMFETAMINE	ICSR
											1{DF} - Intramuscular])	DIMESYLATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 30mg - n/a]),	

1.11.2022 1	2.04							Run	Line L	isting Report			
												[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 10mg -	
EU-EC- 10010213985	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	n/a]) Not reported	ICSR
EU-EC- 10010213992	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010214013	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Henoch-Schonlein purpura (12d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010214092	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (25d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved	(COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010214148	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010214150	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010214166	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010214377	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1h - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Myalgia (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])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010214400	04/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (30min - Recovered/Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Unknown - ), Pallor (30min - Recovered/Resolved - ), Peripheral coldness (n/a - Recovered/Resolved - ), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), Pulse volume decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Weight decreased (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010214409	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovered/Resolved	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010214426	04/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1wk - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL -	Not reported	ICSI
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),	Intramuscular])		
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010214593	04/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - ), Headache (n/a -	COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICS</u>
										Recovering/Resolving -),  Lymphadenopathy (n/a - Recovering/Resolving	I{UF} - n/a])		
EU-EC- 10010214778	04/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Loss of consciousness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),	immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSI
										Seizure (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010202450	03/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC-	03/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY	Not reported	ICSI
10010202452	,,			Economic Area	available	Years				Unknown - Other Medically Important Condition), Vaccination failure	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC-	03/10/2021	Spontaneous	Non	European	Not	12-17	Not	Fomalo	No	(n/a - Unknown - Other Medically Important Condition)	COMIRNATY	Not reported	ICCI
10010202496	03/10/2021	Spontaneous		Economic	Not available	Years	Specified	Female	INO	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICS</u>
										Resolved - ),  Malaise (n/a - Recovering/Resolving - ),			
										Migraine (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	02/10/2021	Spontaneous	Non	Europoon	Not	12-17	Not	Female	No	Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY	Not reported	ICCI
10010202528	03/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Specified	remale	INO	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010202529	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not	Not reported	ICSF
										Nausea (n/a - Recovering/Resolving - ),	applicable - [n/a -		
										Presyncope (n/a - Recovering/Resolving - ),			
										Pyrexia (30min - Recovered/Resolved - ),			
EU-EC-	03/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Vomiting (n/a - Recovering/Resolving - ) Amenorrhoea (n/a -	COMIRNATY	NOT AVAILABLE (C - n/a - n/a	ICci
10010202543	30, 10, 2021	Sportaineous		Economic	available	Years	Specified	. SmalC		Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not	- [n/a - n/a - n/a])	100

											applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010202673	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Burning sensation (1d - Recovered/Resolved -), Erythema (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010202676	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - )  Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
EU-EC- 10010202819	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (1d - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										Injection site pruritus (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 - ), Rash pruritic (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010202835	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site erythema (n/a - Recovered/Resolved - ), Injection site inflammation (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Recovering/Resolving - ), Injection site swelling (n/a - Recovering/Resolving - )			
EU-EC- 10010202841	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ear discomfort (n/a - Not Recovered/Not Resolved - ), Tinnitus (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010202861	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Chills (0d - Recovered/Resolved - ), Dyspnoea (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										- ), Headache (1d - Recovered/Resolved - ), Malaise (n/a -			
										Recovering/Resolving - ), Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (0d - Recovered/Resolved - ), Pyrexia (n/a - Recovering/Resolving			
EU-EC-	02/10/2021	Sporton	Non	Europe	Not	12.17	Not	Eom: I-	No	Vomiting (0d - Recovered/Resolved - )	COMIDNATY	Not reported	Iccr
10010202874	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving - ), Diarrhoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -),			

0.11.2022 1	2.04							Kulli	LIIIE L	isting Report			
EU-EC- 10010202913		Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Recovering/Resolving - ) Chills (1d - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (2d - Recovered/Resolved - ), Injection site pain (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Nausea (1d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Tremor (3h - Recovered/Resolved - )			
EU-EC- 10010202953	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pityriasis rosea (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- 10010203019	03/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved - ), Polymenorrhoea (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- 10010203027	03/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (9d - Not Recovered/Not Resolved - ), Decreased appetite (9d - Not Recovered/Not Resolved - ), Hypersensitivity (n/a - Not Recovered/Not Resolved - ), Malaise (9d - Not Recovered/Not Resolved - ), Pyrexia (14d - Recovered/Resolved - ), Rhinitis allergic (n/a	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010203058	03/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Not Recovered/Not Resolved - ) Arthralgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010203076	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (n/a - Unknown - )	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010203094	03/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving - ), Cough (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (4d - Recovered/Resolved - ), Injection site erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

30.11.2022 1	2.07							IXuIII	LINE LI	isting Report			
										Recovering/Resolving - ), Injection site inflammation (n/a - Recovering/Resolving - ), Injection site pain			
										(n/a - Recovering/Resolving - ), Injection site swelling (n/a -			
										Recovering/Resolving - ), Injection site warmth (n/a - Recovering/Resolving			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (3d - Recovered/Resolved - ), Nasopharyngitis (n/a			
										- Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not			
EU-EC- 10010203139	03/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Body temperature increased (1d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (1d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Syncope (5s - Recovered/Resolved - )			
EU-EC- 10010203141	03/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Paraesthesia oral (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010203185	03/10/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - ) Arthralgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Chills (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Hyperpyrexia (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Recovering/Resolving - ),			
ELLEC	02/10/2021	Chantanaous	Non	European	Not	12 17	Adult	Eomalo	No	Nausea (n/a - Recovering/Resolving - )	COMIDNATY	Not reported	ICCD
EU-EC- 10010203215	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female		Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU EC	02/40/202	Canal	Nan	Francisco de la constanta de l	Net	12.47	Nat	F '	No.	(n/a - Recovered/Resolved - )	COMIDNIATY	TETLIANI ECTRADIC	Ices
EU-EC- 10010203256	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female		Intermenstrual bleeding (21d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC-	03/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Abdominal pain (n/a		Not reported	ICSR

80.11.2022 1	12.04							Ruii i	-IIIe L	isting Report			
10010203273			Healthcare Professional	Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010203275	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Chest pain (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Recovered/Not Resolved - ), Injection site pain (n/a - Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved - )			
EU-EC- 10010203311	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Herpes zoster (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- 10010203344	03/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010203347	03/10/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site	COMIRNATY [TOZINAMERAN] (S - COVID-1) immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovered/Not Resolved - )			
EU-EC- 10010203362	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
			FIOLESSIONAL	Alea						Headache (2d - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (2d -			
										Recovered/Resolved			
										Malaise (1d - Recovered/Resolved - ),			
										Myalgia (1d - Recovered/Resolved - )			
EU-EC- 10010203397	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ),	COVID-19	Not reported	ICS
										Chills (2h - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Heart rate increased (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010203414	03/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[SOMATROPIN] (C - n/a - Dose not changed - [n/a - n/a - n/a])	ICS
										Headache (3d - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	7,27	
										Injection site pain (3d - Recovered/Resolved			
										- ), Malaise (3d -			
										Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved			
EU-EC-	02/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	- ) Capillary fragility	COMIRNATY	Not reported	ICS
10010198789			Healthcare Professional	Economic Area	available	Years	Specified			(n/a - Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a -		
										Erythema (n/a - Recovered/Resolved	[n/a - n/a - Intramuscular])		
EU-EC- 10010198982	02/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Burning sensation (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Flushing (n/a - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - Intramuscular])		
										Lip swelling (n/a - Recovered/Resolved - ),			
										Rash (n/a - Recovered/Resolved - ),			
										Tongue oedema (n/a			
EU-EC-	02/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved - )  Menstruation delayed	COMIRNATY	Not reported	ICS
10010199046			Healthcare	Economic Area	available	Years	Specified			(n/a - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010199072	02/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
										Breast swelling (n/a - Recovered/Resolved	immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010200608	02/10/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI

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				Area						- ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving			
EU-EC- 10010200628	02/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haemophagocytic lymphohistiocytosis (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10010200730	02/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site discolouration (n/a - Recovered/Resolved With Sequelae - ), Skin discolouration (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010200736	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	With Sequelae - ) Neck pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10010200959	02/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Injection site pain (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10010200982	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening), Pain in extremity (n/a - Not Recovered/Not Resolved - Life Threatening), Paraesthesia (n/a - Not Recovered/Not Resolved - Life Threatening), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening), Somnolence (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010201034	02/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010201295	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Injection site haematoma (n/a - Not Recovered/Not Resolved - ), 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 - ), Injection site swelling (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

0.11.2022 1	2.04							Run I	_ine L	isting Report			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - )			
EU-EC- 10010201300	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular!)	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - n/a - Oral])	ICSR
EU-EC- 10010201608	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ), Injection site pain (n/a - Recovering/Resolving - ), Muscle spasms (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Rhinorrhoea (n/a - Recovering/Resolving - ), Sneezing (n/a -	Intramuscular]) COMIRNATY CONCENTRATE FOR DISPERSION FOR INIECTION [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010201617	02/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving -) Gait disturbance (24h - Recovered/Resolved - ), Nausea (24h - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010201622	02/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ), Syncope (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010201690	02/10/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010202030		Spontaneous	Healthcare Professional	European Economic	Not available Not available	12-17 Years	Not Specified  Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved - ), Chills (3h - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Malaise (3d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Arthralgia (1d - Recovered/Resolved - ), Body temperature increased (3d - Recovered/Resolved - ), Chest pain (n/a - Recovered/Resolved - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Headache (2h - Recovered/Resolved - ), Malaise (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

0.11.2022 1	2.04							Run I	Line L	₋isting Report			
										Recovered/Resolved			
										Myalgia (2d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - )			
EU-EC- 10010202092	02/10/2021	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 immunisation - Not	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
EU EO	02/40/2024		N			12.17		F I		Tinnitus (n/a - Not Recovered/Not Resolved - )	COMPNATA		TOSE
EU-EC- 10010202114	02/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010202171	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Chills (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 - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010202178	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010202187	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Rash pruritic (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010202229	02/10/2021	Spontaneous	Non Healthcare Professional	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	Not reported	ICSR
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
EU-EC- 10010202242	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										(n/a - Not Recovered/Not	1{DF} - n/a])		

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										Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010202249	02/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010187434	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010188683	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010188826	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - )  Lymph node pain (n/a - Not Recovered/Not Resolved - ),  Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010188842	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ) Headache (2d - Recovered/Resolved - ), Injection site pain (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved			
EU-EC- 10010188843	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Vomiting (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010188847	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10010188899	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSF
EU-EC- 10010188902	01/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - ), Swelling (n/a - Not Recovered/Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSF
EU-EC- 10010188971	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Decreased appetite (n/a - Recovered/Resolved With Sequelae - ), Nausea (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010188977	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	With Sequelae - ) Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperpyrexia (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF

	<u> </u>		<u> </u>							Caused/Prolonged Hospitalisation)			
EU-EC- 10010189032	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Supraventricular extrasystoles (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010189259	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea exertional (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
EU-EC- 10010189456	01/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (8d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010189463	01/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Clonus (0d - Recovered/Resolved - ), Cold sweat (0d - Recovered/Resolved - ), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Pallor (0d - Recovered/Resolved - ), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010190057	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010190066	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (2d - Recovered/Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010190077	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010190078	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Pain in extremity (2d - Recovered/Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010190811	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010191470	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Hypersomnia (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	(COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010191524	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

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										- ), Loss of personal independence in daily activities (n/a - Unknown - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pain (n/a - Recovering/Resolving - ),			
										Vomiting (1d - Recovered/Resolved - )			
EU-EC- 10010191528	01/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Area						Polymenorrhoea (n/a - Unknown - ),	Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Vaginal haemorrhage (n/a - Unknown - )			
EU-EC- 10010191605	01/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	- Officiowity)		
EU-EC- 10010191637	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (7d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Chills (7d - Recovered/Resolved - Disabling),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Dizziness (7d - Recovered/Resolved - Disabling),			
										Fatigue (7d - Recovered/Resolved - Disabling),			
										Headache (7d - Recovered/Resolved - Disabling),			
										Malaise (7d - Recovered/Resolved - Disabling),			
										Myalgia (7d - Recovered/Resolved - Disabling),			
										Pyrexia (7d - Recovered/Resolved - Disabling),			
										Respiratory disorder (7d - Recovered/Resolved - Disabling)			
EU-EC- 10010191738	01/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Resolved - ),  Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Polymenorrhoea (n/a - Unknown - )			
EU-EC- 10010191739	01/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Агеа						- ), Menstruation irregular (n/a - Recovering/Resolving - ),	Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Polymenorrhoea (n/a - Unknown - )			
EU-EC- 10010191807	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1/DE3 - n/a]	Not reported	ICSR
EU-EC- 10010191809	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC-	01/10/2021	Spontaneous		European	Not	12-17	Not	Female	No	Fatigue (n/a -	1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10010191818			Healthcare Professional		available	Years	Specified			Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19		

30.11.2022 1	2.04							IXUII L	-IIIe L	isting Report			
										Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ), Malaise (2d - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Myalgia (2d - Recovered/Resolved			
EU-EC- 10010191834	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Arthralgia (2d - Recovered/Resolved - ), Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (5d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ZOELY 2.5 MG/1.5 MG FILM-COATED TABLETS [LACTOSE MONOHYDRATE, NOMEGESTROL ACETATE, ESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]),  [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - n/a]),  [PEPPERMINT OIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Pyrexia (n/a - Not Recovered/Not			
EU-EC-	01/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Resolved - ) Body temperature	COMIRNATY	Not reported	ICSR
10010192774			Healthcare Professional	Economic Area	available	Years	Specified			increased (2d - Recovered/Resolved - ), Chills (30h - Recovered/Resolved - ), Extensive swelling of vaccinated limb (27h - Recovered/Resolved - ), Fatigue (2d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ), Injection site pain (27h - Recovered/Resolved - ), Injection site pustule (27h - Recovered/Resolved - ), Injection site swelling (27h - Recovered/Resolved - ), Malaise (96h - Recovered/Resolved - ), Malaise (96h - Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Myalgia (4d - Recovered/Resolved - ), Rhinitis (n/a - Recovered/Resolved			
	01/10/2021	Spontaneous		European	Not	12-17 Years	Not Specified	Female	No	- ) Herpes zoster (n/a -	COMIRNATY	Not reported	ICSR
10010192778			Healthcare Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
10010192796		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (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- 10010193018	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye infection (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Domania (a.l.			
										Pyrexia (n/a - Unknown - )			
EU-EC- 10010193274	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICS</u>
										Nausea (1wk - Recovered/Resolved - )			
EU-EC- 10010193300	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
EU-EC- 10010193407	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Extensive swelling of vaccinated limb (n/a - Unknown - Other Medically Important Condition)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10010193606	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Allergic respiratory symptom (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSF
										Fatigue (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Infected bite (n/a - Unknown - Other Medically Important			
EU-EC- 10010194065	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition)  Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010194098	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010194613	01/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010194658	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema nodosum (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010194778	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Pelvic pain (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	01/10/2021	Spontaneous		European	Not	12-17	Not	Male	No	Pyrexia (n/a - Recovering/Resolving - ) Cough (n/a - Not	COMIRNATY	[AZELASTINE	ICSF
10010194799			Healthcare Professional	Economic	available	Years	Specified			Recovered/Not Resolved - ), Dyspnoea (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),  [SALBUTAMOL, SALBUTAMOL	
	1									Recovered/Not	1{DF} - n/a])	SULFATE] (C - n/a - n/a - [n/a	

).11.2022 1	2.04							Run	Line L	isting Report			
										Not Recovered/Not Resolved - ),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (3d - Recovered/Resolved			
EU-EC- 10010194821	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [2d - n/a - n/a])	ICSR
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010195105	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Scrotal pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010195433	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY	Not reported	ICSR
EU-EC- 10010195624	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195629	01/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195632	01/10/2021	Spontaneous		European Economic Area	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} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195643	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195646	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved - ) Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010195857	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Malaise (n/a - Recovering/Resolving - ), Musculoskeletal stiffness (3h - Recovered/Resolved - ),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Myalgia (3h - Recovered/Resolved - ), Speech disorder (3h - Recovered/Resolved			
EU-EC- 10010195904	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthmatic crisis (n/a Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195905	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Recovered/Resolved		Not reported	ICSR
EU-EC-	01/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	- ) Menstruation delayed	- Intramuscular])	Not reported	ICSR

0.11.2022 1	2.04							Runi	Line L	isting Report			
10010195909			Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010195944	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195977	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010195996	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (3d - Recovered/Resolved - ), Varicella (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010196004	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Vaccination site pruritus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010196034	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010196112	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010196124	01/10/2021	Spontaneous	Healthcare Professional	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- 10010196151	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea exertional (3wk - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
10010196618		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010196624	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (10d - Recovered/Resolved - ),  Dyspnoea (10d - Recovered/Resolved - ),  Rash (10d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010196632	01/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010196676	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010196681	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypotension (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010196721	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Not Recovered/Not Resolved - ) Ecchymosis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010196916	01/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSI
EU-EC- 10010197197	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Dizziness (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010197201	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Dizziness (0d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Injection site haematoma (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010197223	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Malaise (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010197531	01/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Lymphadenopathy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010197567	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (0d - Recovering/Resolving - ), Menstrual disorder (0d - Recovering/Resolving - )	COMIRNATY	Not reported	ICSF
EU-EC- 10010197673	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Petechiae (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010197805	01/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CHLORPHENAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C - Headache - n/a - [n/a - n/a - Oral]), [GUAIFENESIN] (C - Influenza like illness - n/a - [n/a - n/a - Oral]), [IBUPROFEN, NAPROXEN, NAPROXEN SODIUM] (C - Menstrual disorder - n/a - [n/a - n/a - Oral])	
EU-EC- 10010197884	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovering/Resolving - ), Urticaria (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [n/a -	[LORATADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010198552	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (13d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010198558	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (113d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010198694	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (n/a - Unknown - ), Pruritus (n/a - Unknown - ), Rash (3d - Not Recovered/Not	[[//a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010199462	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Chills (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

.11.2022 1	2.04							Run	_ine L	isting Report			
										Pyrexia (n/a - Unknown - )	immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010199464	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
:U-EC- .0010199469	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a -	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0010199477	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown - )  Pyrexia (n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
U-EC- 0010199486	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0010199502	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0010199510	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown - ) Axillary pain (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Vaccination site lymphadenopathy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	ICS
U-EC- 0010199513	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),  GARDASIL SUSPENSION FOR INJECTION [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 16 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 6 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 6 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, AMORPHOUS	Not reported	

0.11.2022 1	2.04							Kulli	-iiie L	isting Report			
											PAPILLOMAVIRUS TYPE 6 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN] (S - n/a - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010199514	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (5d - Recovered/Resolved - ), Malaise (5d - Recovered/Resolved - ), Pyrexia (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010199516	01/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiomyopathy acute (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010199553	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010199644	01/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown - ), Vaccination site inflammation (n/a - Unknown - ), Vaccination site joint erythema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010199686	01/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Ma <b>l</b> e	No	Abdominal discomfort (n/a - Unknown - ),  Decreased appetite (n/a - Unknown - ),  Fatigue (n/a - Unknown - ),  Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010199689	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area		12-17 Years	Adolescent	Ma <b>l</b> e	No	Unknown - ) Abdominal pain (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (2d - Unknown - ), Vomiting (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010199734	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown - ) Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010199756	01/10/2021	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- 10010199760	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010199762	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dysgeusia (n/a - Recovering/Resolving - ), Hyposmia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC- 10010199770	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-	01/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Dizziness (1d -	COMIRNATY	Not reported	ICSR

J.11.2022 I	12.07							ixuii	LIIIC L	Isting Report			
10010199780			Professional	Economic Area	available	Years				Recovered/Resolved - ), Headache (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010199782	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010199789	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010199826	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Erythema (n/a - Recovering/Resolving - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010199836	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010199843	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Urticaria (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10010199864	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010199904	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (2d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010199906	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Diarrhoea (2d - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010200323	01/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved - ), Fatigue (11d - Not Recovered/Not Resolved - ), Headache (6d - Recovered/Resolved - ), Headache (7d - Recovered/Resolved - ), Nausea (3d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Tachycardia (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

J.11.2022 I		I	I	l	I	I	I		 	Recovered/Resolved	I	I	1
EU-EC-	01/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	- ) Anaphylactic reaction	COMIRNATY	Not reported	ICSI
10010200325		·	Professional		available	Years				(15min -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	,	
										Urticaria (15min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010200326	01/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
										(n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010200490	01/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSF
EU-EC- 10010170357	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC-	30/09/2021	Spontaneous		European	Not	12-17	Not	Male	No	Resolved - ) Arthralgia (n/a -	COMIRNATY	Not reported	ICSF
10010170369			Healthcare Professional	Economic Area	available	Years	Specified			- ), Chills (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										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 - )			
EU-EC- 10010170372	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved - ), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Recovered/Resolved - ),	1{DF} - n/a])		
										Injection site swelling (4d - Recovered/Resolved - ),			
										Myalgia (3d - Recovered/Resolved - )			
EU-EC- 10010170597	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSF
										Headache (n/a - Recovering/Resolving - ),	[n/a3mL - Intramuscular])		
										Pain (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10010170616	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (8d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSF
										- ),	[n/a3mL - Intramuscular])		
										Malaise (8d - Recovered/Resolved - ),			
										Pyrexia (8d - Recovered/Resolved - ),			
										Vertigo (8d -			

		I	I	I	I	I	I			Recovered/Resolved	I	I	I
EU-EC-	30/09/2021	Spontaneous		European	Not	12-17	Not	Female	No	- ) Arthralgia (n/a - Not		Not reported	IC
10010172597			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -		
										Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),	Intramuscular])		
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 1001017252  EU-EC- 10010172913	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	10
										Headache (3d - Recovered/Resolved -),			
										Pain (3d - Recovered/Resolved - )			
	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Burning sensation (n/a - Recovering/Resolving - ),	immunisation - n/a -	Not reported	10
										Pain in extremity (n/a - Recovering/Resolving -)	[n/a - 1{DF} - Intramuscular])		
	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	<u>I(</u>
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),	[n/a - 1{DF} - Intramuscular])		
										Palatal oedema (n/a - Not Recovered/Not Resolved - ),			
	20 (00 (2021					12.17				Pyrexia (n/a - Not Recovered/Not Resolved - )	COMPUT		
	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>I</u>
										Injury (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	.3mL - Intramuscular])		
EU-EC- 10010173133	30/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	Ī
										Heart rate increased (n/a - Recovered/Resolved With Sequelae - ),			
										Influenza like illness (n/a - Recovered/Resolved			
:U-EC- 0010173160	30/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Ma <b>l</b> e	No	With Sequelae - )  Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	1
										Medically Important Condition), Malaise (n/a -	applicable - [1d - n/a - n/a])		
										Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-	30/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Dyspnoea (n/a -	TOZINAMERAN	Not reported	Ī

30.11.2022 1	2.04							Run I	Ine L	isting Report			
10010173232			Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Headache (n/a - Recovered/Resolved			
										Pain in extremity (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010173516	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved With Sequelae - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - ),	Intramuscular])		
										Myalgia (1mo - Recovered/Resolved - )			
EU-EC- 10010173742	30/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Fall (n/a - Unknown - Other Medically Important Condition),	1,701)		
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Pallor (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010173834	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Supraventricular tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010173839	30/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010174620	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S -	[LITHIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAZOSIN] (C - n/a - n/a -	ICSR
				Alea						Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged		[r/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Hospitalisation),  Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010174758	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Nausea (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010174967	30/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]	BUDESONIDE [BUDESONIDE] (C - Crohn's disease - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC-	30/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Condition) Influenza like illness	- n/a])  COMIRNATY	Not reported	ICSR

).11.2022 1	2.04							Run	Line L	isting Report			
10010175154				Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010175295	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010175450	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010175452	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - )	COMIRNATY	Not reported	ICSR
EU-EC- 10010175468	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010175470	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010175497	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010175865	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - )  Menstrual disorder (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- 10010175887	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Injection site pain (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving - ), Nausea (2h -			
										Recovered/Resolved - ), Syncope (2h -			
EU-EC-	30/09/2021	Spontaneous		European	Not	12-17	Not	Female	No	Recovered/Resolved - ) Chills (n/a - Not	COMIRNATY	[COLECALCIFEROL] (C - n/a -	ICSR
10010175914			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
										Resolved - ),  Fatigue (n/a - Recovering/Resolving			
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC-		Spontaneous	1	European	Not	12-17	Not	Female	No	Body temperature	COMIRNATY	Not reported	ICSR 62/6

0.11.2022 1	2.04							Ruii L	-IIIe L	isting Report			
10010175916			Healthcare Professional	Economic Area	available	Years	Specified			increased (2d - Recovered/Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not		
										Cough (21d - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (1d - Recovered/Resolved			
EU-EC- 10010175944	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ),	COVID-19	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010175945	30/09/2021	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	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Dizziness (2h - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (2d - Recovered/Resolved - ),			
										Headache (2d - Recovered/Resolved - ),			
										Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ),			
										Malaise (2h - Recovered/Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (8h - Recovered/Resolved - ),			
										Pyrexia (17h - Recovered/Resolved - )			
EU-EC- 10010176327	30/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Conjunctival hyperaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Rot reported  [ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Eyelid disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} -		
										Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Feeding disorder (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
										Lip swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Periorbital swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Reduced facial expression (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation)			_

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EU-EC- 10010176444	30/09/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [0d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010176574	30/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (2d - Recovering/Resolving - ), Influenza like illness (2d - Recovering/Resolving - ), Local reaction (2d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010176583	30/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Life Threatening,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010176625	30/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (5d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR



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