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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	(Drug Char - Indication PT -	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICS For
EU-EC- 10011244986	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (0d - Unknown -), Nausea (1d - Not Recovered/Not Resolved -), Pyrexia (1d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		IC
EU-EC- 10011245012	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Headache (Od - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Pyrexia (Od - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10011245028	12/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	IC
EU-EC- 10011245092	12/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	-) Pyrexia (0d - Recovered/Resolved	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	IC
EU-EC- 10011245097	12/01/2022	Spontaneous	Professional Non Healthcare Professional	Area European Economic	Not available	12-17 Years	Adolescent	Female	No	Vomiting (0d - Recovered/Resolved	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	IC
EU-EC- 10011245098	12/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Vaccination site reaction (2d - Recovered/Resolved	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10011245116	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	-) Injection site pain (0d - Not Recovered/Not Resolved -), Injection site swelling (0d - Not Recovered/Not Resolved -), Pyrexia (0d - Not Recovered/Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10011245134	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -), Headache (1d - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245137	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (4d - Not Recovered/Not Resolved -), Headache (4d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245144	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -) Cough (2d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Injection site swelling (1d - Recovering/Resolving -), Lymphadenopathy (2d - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS

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EU-EC- 10011245155	12/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Resolved -)			
EU-EC- 10011245157	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245191	12/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245198	12/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Cough (1d - Not Recovered/Not Resolved -), Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245209	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245220	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245240	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Fatigue (2d - Recovering/Resolving -), Headache (2d - Recovering/Resolving -), Myalgia (1d - Recovering/Resolving		Not reported	ICS
EU-EC- 10011245245	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (4d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
	12 (21 (222					12.12				Headache (32d - Recovered/Resolved			
EU-EC- 10011245255	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245278		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved), Fatigue (3d - Recovered/Resolved), Headache (2d - Recovered/Resolved), Limb discomfort (2d - Recovered/Resolved), Myalgia (2d - Recovered/Resolved), Myalgia (1d - Recovered/Resolved), Pyrexia (1d - Recovered/Resolved), Vaccination site reaction (3d - Recovered/Resolved) Vaccination site reaction (3d - Recovered/Resolved) Arrhythmia (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
10011245290		Spontaneous	Healthcare Professional		Not available	Years			No	Arrhythmia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICS
EU-EC- 10011245327	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Injection site pain (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	mot reported	ICS
EU-EC- 10011245333	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245339	12/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011245347	12/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
EU-EC- 10011245354	12/01/2022	Spontaneous	Professional Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	-) Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Injection site	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF

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										erythema (n/a - Unknown -),			
										Myalgia (n/a - Unknown -),			
										Nausea (n/a - Unknown -)			
EU-EC- 10011245407	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Injection site pain (3d - Recovered/Resolved			
										Limb discomfort (2d			
										Recovered/Resolved -), Pyrexia (1d -			
EU-EC-		Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved -) Dyspnoea (9d - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011245426			Healthcare Professional	Economic Area		Years				Recovered/Not Resolved -), Fatigue (1d -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Resolved			
										Injection site pain (2d - Recovered/Resolved -),			
										Malaise (0d - Recovering/Resolving			
										Tachycardia (9d - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Recovered/Resolved			
EU-EC- 10011245431	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Influenza (1d - Recovered/Resolved -),	· · · ·		
										Malaise (1d - Recovered/Resolved			
EU-EC- 10011245462	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (2d - Recovered/Resolved -),			
										Headache (4d - Recovering/Resolving			
										Injection site pain (1d -			
										Recovered/Resolved -), Limb discomfort (0d			
										Recovered/Resolved			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011245466		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site swelling (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011245470	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Influenza (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011245471	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (2d - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved			
										Injection site pain (3d -			
										Recovered/Resolved -),			

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										Nausea (2d - Recovered/Resolved -), Vomiting (1d -			
EU-EC- 10011245476	12/01/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Headache (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Alea						-), Injection site pain (2d - Recovered/Resolved -),	- n/a - n/a])		
										Injection site pain (3d - Recovered/Resolved			
EU-EC- 10011245493	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (0d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245496	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -), Malaise (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	12/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved -) Fatigue (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011245506	12,01,2022	Sportaricous	Healthcare Professional	Economic	Not available	Years	radicseciie	T TORC		Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	10310
EU-EC- 10011245560	12/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Vaccination site reaction (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245562	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (8d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (8d - Recovered/Resolved -),			
511.50	12/01/2022					10.17				Nausea (8d - Recovered/Resolved -)			1000
EU-EC- 10011245566		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011245709	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Vaccination site reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245764	12/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Not Recovered/Not Resolved -), Limb discomfort (1d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	12/01/2022	Spontaneous		European	Not available		Adolescent	Male	No	- Not Recovered/Not Resolved -) Pyrexia (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011245784 EU-EC- 10011245797	12/01/2022	Spontaneous	Healthcare Professional Non Healthcare	Economic Area European Economic	Not available	Years 12-17 Years	Adolescent	Male	No	-) Chills (1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional							-), Headache (1d - Recovered/Resolved -),	- n/a - n/a])		
										Injection site pain (2d - Recovering/Resolving			
										-), Lymphadenopathy (1d - Not Recovered/Not Resolved -)			
EU-EC- 10011245838	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245862	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011245877	12/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovered/Resolved -)	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245880	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Cough (42d - Not Recovered/Not Resolved -), Dyspnoea (42d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	11/01/2022	Spontancour	Non	Furancan	Not available	12-17	Adolescent	Male	No	Recovered/Not Resolved -) Arrhythmia (25d -	COMIRNATY ITOZINAMEDANI	Not reported	ICCD
10011213842	11/01/2022	Spontaneous	Healthcare Professional	Economic	not available	Years	Audiescent	male	INO	Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	nocreported	ICSR
										Pericardial effusion (n/a -			

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										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011213843	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (7d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011213857	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011213861	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster meningitis (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011213863	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011213877	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (6d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011213878	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (81d - Recovered/Resolved -), Hyperhidrosis (81d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC-	11/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved -) Myalgia (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011213879 EU-EC-		Spontaneous	Healthcare Professional	Economic Area European	Not available	Years 12-17	Adolescent	Female	No	Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]		ICSI
10011213882	11,01,2022	эропшисов		Economic	Not available	Years	Addrescent	remaie			(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	1031
				_						Recovered/Not Resolved -)			
EU-EC- 10011213885		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Rash (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	·	ICSF
EU-EC- 10011213888		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Menstrual disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011213894	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Menstrual disorder (n/a - Recovering/Resolving -)			
EU-EC- 10011213895	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (2d - Recovered/Resolved -), Dizziness (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Resolved -), Fatigue (32d -			
										Recovered/Resolved -), Headache (2d -			
										Recovered/Resolved -), Injection site erythema (2d -			
										Recovered/Resolved -), Injection site pain			
										(2d - Recovered/Resolved -),			
										Lymphadenopathy (2d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011213904	11/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (6d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011213910	11/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Adolescent	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Chills (1d - Recovering/Resolving -),			
										Dizziness (0d - Recovered/Resolved -), Dyspnoea (0d -			
										Recovering/Resolving			

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										- Other Medically Important Condition),			
										Injection site pain (1d - Recovering/Resolving			
EU-EC- 10011213913	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (19d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Syncope (19d - Recovering/Resolving - Other Medically Important Condition)			
:U-EC- .0011213924	11/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Raynaud's phenomenon (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0011213925	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Glossodynia (0d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Injection site pain (2d - Recovering/Resolving -),			
										Malaise (1d - Recovered/Resolved -)			
U-EC- 0011213927		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	-)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
:U-EC- :0011214087	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICS</u>
EU-EC- 10011214115	11/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 10011214346	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	[BETAMETHASONE DIPROPIONATE, CALCIPOTRIOL MONOHYDRATE, BETAMETHASONE, CALCIPOTRIOL] (C - n/a - n/a - [n/a - n/a - Cutaneous])	ICS
EU-EC- 10011214347	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		ICS
										Glare (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011214450	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011214984	11/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011215176	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Vaccination site bruising (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Unknown -), Vaccination site pruritus (n/a - Unknown -)			
EU-EC- 10011215210	11/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICS
										Chest pain (n/a - Unknown - Other Medically Important Condition),			

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											Decreased appetite (n/a - Unknown - Other Medically Important Condition),			
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Headache (n/a - Unknown - Other Medically Important Condition),			
											Palpitations (2d - Recovered/Resolved - Other Medically Important Condition),			
											Pyrexia (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011215219	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Decreased appetite (n/a - Unknown - Other Medically Important Condition),			
											Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10011215732	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	EU-EC- 10011216008	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Back pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
											Chest pain (n/a - Recovered/Resolved -),			
											Fatigue (n/a - Recovered/Resolved -),			
											Feeling cold (n/a - Recovered/Resolved -),			
											Headache (n/a - Recovered/Resolved -),			
											Lymphadenopathy (n/a - Recovered/Resolved			
											-), Pyrexia (n/a -			
											Recovered/Resolved -), Tremor (n/a -			
											Recovered/Resolved -), Vaccination site pain			
											(n/a - Recovered/Resolved -),			
	EU-EC-	11/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Vomiting (n/a - Recovered/Resolved -) Dysphagia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
	10011216099	-1/01/2022	-portaneous	Professional		not available	Years	, worestell	i∵iai€	140		(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	постеронец	<u>1COK</u>
											Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important			
											Condition),			1

										Pharyngitis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Respiratory tract infection (n/a -			
										Recovered/Resolved - Other Medically Important Condition), Sick leave (1d - Recovered/Resolved - Other Medically Important Condition), Sick leave (2d -			
										Recovered/Resolved - Other Medically Important Condition), Sick leave (31d - Recovered/Resolved - Other Medically Important Condition),			
										Sick leave (3d - Recovered/Resolved - Other Medically			
EU-EC- 10011216102	11/01/2022	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Male	No	Important Condition) Myocarditis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation, Obesity - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011216118	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Feeling hot (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -),			
EU-EC-	11/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Myalgia (n/a - Unknown -) Heavy menstrual	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
10011216472			Healthcare Professional	Economic Area		Years	Specified			bleeding (n/a - Not Recovered/Not Resolved -)	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011216475	11/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[FLUTICASONE PROPIONATE, SALMETEROL.] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL.] (C - Asthma - n/a -)	ICSR
										Fatigue (n/a - Unknown -), Gait disturbance (n/a			
										- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Respiratory tract infection (n/a - Unknown -), Walking aid user (n/a			
										- Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10011216524	11/01/2022	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Female	No	Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011216547	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a -			

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										Unknown - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash erythematous (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011216552	11/01/2022	Spontaneous		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 - n/a -	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	n/a])		
										Pain in extremity (n/a - Recovering/Resolving -)			
EU-EC- 10011216621	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (14d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Nausea (14d - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (14d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011216632	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011216807	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (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- 10011216963	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling cold (5min - Recovered/Resolved -), Headache (5min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Syncope (5min - Recovered/Resolved			
EU-EC- 10011216964	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Syncope (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved -)	n/a]) ·		
EU-EC- 10011217174	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011217180		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Myopericarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011217181	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Tachycardia (13d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011217194	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Tachycardia (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-	11/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10011217330			Professional	Economic Area		Years				Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011217617	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (3mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011217732	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011218521	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011218711	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	 	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Resolved -), Myocarditis (2d - Not Recovered/Not Resolved -)			
EU-EC- 10011218805	11/01/2022	Spontaneous		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 - Intramuscular])	Not reported	ICSR
EU-EC- 10011218806	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ASCORBIC ACID] (C - n/a - n/a -), [VITAMIN D] (C - n/a - n/a -)	ICSR
EU-EC- 10011218966	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Anosmia (n/a - Recovering/Resolving -), Arthralgia (21d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved -), Disturbance in attention (n/a - Not			
										Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving			
										Headache (34d - Recovered/Resolved -),			
										Malaise (14d - Recovered/Resolved -),			
										Nausea (21d - Recovered/Resolved -), Pyrexia (n/a -			
EU-EC- 10011219305	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Hospitalisation), Dizziness postural (n/a - Unknown - Caused/Prolonged Hospitalisation),	n/a])		
										Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011219380	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Insomnia (n/a - Not Recovered/Not			
										Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011219414	11/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Dyspepsia (n/a - Recovered/Resolved With Sequelae -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	KEPPRA [LEVETIRACETAM] (C	<u>ICSR</u>

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				Economic Area						Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])	- Epilepsy - n/a - [n/a - n/a - n/a])	
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011219770	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011220146	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011220224	11/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Discomfort (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011220227	11/01/2022	Spontaneous	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Electrocardiogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myocardial necrosis marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 10011220266	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
				/ I Cu						Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Chalomijy		
EU-EC- 10011220315	11/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dehydration (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Flatulence (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)			
EU-EC- 10011220321	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Diarrhoea (n/a - Unknown -),			
										Dyspnoea (n/a - Unknown -),			

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										Muscle spasms (n/a - Unknown -),			
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a -			
										Unknown -), Vomiting (n/a -			
EU-EC-		Spontaneous	Healthcare	Non	Not available		Not	Male	No	Unknown -) Blood creatine	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011220322			Professional	European Economic Area		Years	Specified			phosphokinase MB increased (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase	(S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])		
										increased (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (11d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Oropharyngeal pain (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Respiratory symptom (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rhinorrhoea (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011220550		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Areflexia (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	Not reported	ICSR
										Asthenia (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B),		
										Gait inability (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED		
										Guillain-Barre syndrome (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (204h	STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP)908/2015,		
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	ÎVÊ-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a])		
										Hyporeflexia (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Muscular weakness (204h - Recovered/Resolved			
										- Caused/Prolonged Hospitalisation, Other Medically Important			

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										Pain in extremity (276h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011220570	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (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- 10011220593	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Hyperhidrosis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011220604	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Dysstasia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Gait disturbance (n/a - Not Recovered/Not Resolved -),			
										Hyperventilation (n/a - Unknown -),			
										Initial insomnia (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Suicide attempt (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011220614	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a -			
										Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a -			
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011220619	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Systemic lupus erythematosus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - n/a])	Not reported	ICSF
EU-EC- 10011220701	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Rash (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
EU-EC- 10011220801	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSF
										Fatigue (n/a - Not Recovered/Not Resolved -),	- n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011221018	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Movement disorder (n/a - Unknown -), Pain (n/a - Unknown			
										Pain (n/a - Unknown -)			
EU-EC- 10011221184	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important			
EU-EC- 10011221189	11/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Chest pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, NORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (50d - Recovered/Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011221208	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011221419	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011221473	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Autonomic neuropathy (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Blood pressure decreased (n/a - Recovering/Resolving -),			
										Dizziness (n/a - Recovering/Resolving -), Feeling abnormal			
										(n/a - Recovering/Resolving -), Heart rate decreased			
										(n/a - Recovering/Resolving -)			
EU-EC- 10011221536	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011221582	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Vulval ulceration (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011221595	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthma (n/a - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - 2{DF} - Intramuscular])	Not reported	ICSR
										Immunisation reaction (n/a - Recovered/Resolved -),			
										Malaise (n/a - Recovered/Resolved -)			
EU-EC- 10011221622	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011221641	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Menstruation delayed	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a -			

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										Not Recovered/Not Resolved -), Tachycardia (n/a -			
										Not Recovered/Not			
EU-EC- 10011221752	11/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Malaise (2h - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
EU-EC- 10011221798	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Blood pressure increased (n/a - Recovered/Resolved - Other Medically	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011221804	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Blood pressure increased (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011221818	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Conjunctivitis (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Lacrimation increased (n/a - Unknown -), Scleral hyperaemia (n/a - Unknown -),			
EU-EC-	11/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Vaccination site pain (n/a - Unknown -) Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011221845	11,01,2022	Sportailesus	Professional			Years	Specified	remale		Recovered/Resolved -), COVID-19 (n/a - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	not reported	10011
										Vaccination site pain (n/a - Recovered/Resolved			
EU-EC- 10011221848	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011221856	11/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (8d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (8d - Recovered/Resolved			
EU-EC-	11/01/2022	Spontaneous	Hoalthcaro	Non	Not available	12-17	Not	Male	No	- Caused/Prolonged Hospitalisation, Other Medically Important Condition) Blood pressure	COMIRNATY [TOZINAMERAN]	Not reported	ICCD
10011221865		,	Professional	European Economic Area		Years	Specified			increased (n/a - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011221878	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Diarrhoea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Dyspnoea (n/a - Unknown -), Myocarditis (n/a -			
										Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown -), Pericarditis (n/a - Unknown - Other			
										Medically Important Condition), Tachycardia (n/a -			
EU-EC- 10011221881	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Feeling abnormal (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other			

										Medically Important Condition)			
EU-EC- 10011222006		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Disturbance in attention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Feeling abnormal (n/a - Unknown -),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nervousness (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (10d - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011222126		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovering/Resolving -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
										(n/a - Recovering/Resolving -), Vaccination site reaction (n/a -			
EU-EC-	11/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Recovering/Resolving -) Diarrhoea (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011222136		Sportarieous	Professional		Not available	Years	Adolescent	indic	NO	Recovered/Not Resolved -), Influenza like illness (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	1001
EU-EC-	11/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Recovered/Not Resolved -) Asthenia (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10011222166		,	Professional			Years	3,2500110			Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Resolved -), Headache (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not			
EU-EC-	11/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Resolved -) Immunisation	COMIRNATY [TOZINAMERAN]	Not reported	ICSF

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10011222245			Healthcare Professional			Years				reaction (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011222356	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011222561	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011222623	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Inappropriate schedule of product administration (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (C - COVID- 19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	
EU-EC- 10011222626	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC-	11/01/2022	Spontaneous	L Lookh oo vo	Non	Not available	12.17	Not	Female	No	Vomiting (n/a - Recovering/Resolving -) Abdominal pain (n/a	COMIDNATY (TOZINAMEDANI)	Not upported	ICCI
10011222688	11/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	remale	INO	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Back pain (n/a - Recovered/Resolved -), Pericarditis (n/a -			
										Recovered/Resolved - Other Medically Important Condition), Tonsillitis (n/a - Recovered/Resolved			
EU-EC- 10011222756	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Livedo reticularis (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
EU-EC- 10011222821	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Migraine (1d - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSE
EU-EC- 10011222899	11/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (0d - Not Recovered/Not Resolved -), Nausea (0d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011223033	11/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -), Injection site swelling (1d - Not Recovered/Not Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC-	11/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Famala	No	(2d - Not Recovered/Not Resolved -) Chills (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	TCCL
10011223035 EU-EC-		Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Adolescent		No	Recovered/Resolved -) Fatigue (1d -	(S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]		ICSR ICSR
10011223190	,,			Economic		Years				Recovered/Resolved -), Feeling hot (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										-), Injection site pain (1d - Recovering/Resolving			
										Limb discomfort (1d Recovered/Resolved),			
										Myalgia (1d - Recovered/Resolved -),			
ELLEC	11/01/2022	Cnortes	Non	Eugene	Not pusible	12.17	Adelaa:	Eor'-	N/~	Pyrexia (0d - Recovered/Resolved -)	COMIDNATY (TOZINAMED CO.)	Not reported	Icc
EU-EC- 10011223220	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Chills (0d - Recovered/Resolved -), Fatigue (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -),			

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										Headache (0d - Recovered/Resolved			
										Influenza (1d - Recovered/Resolved			
										-),			
										Lymphadenopathy (1d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved -),			
										Tachycardia (0d - Recovered/Resolved -),			
										Vaccination site reaction (2d - Recovered/Resolved			
EU-EC- 10011223239	11/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
10011223233			Professional			lcuis				Dizziness (n/a - Unknown -)	- n/a - n/a])		
EU-EC- 10011223276	11/01/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area						Headache (0d - Recovering/Resolving	- n/a - n/a])		
										-),			
										Limb discomfort (1d - Recovered/Resolved			
EU-EC-	11/01/2022	Spontaneous			Not available	12-17	Adolescent	Female	No	-) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011223536			Professional	Area		Years				Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011223955	11/01/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Burning sensation (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional				·			Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash vesicular (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011224108	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011224115	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]),	Not reported	ICSR
										Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	[DIENOGEST, ETHINYLESTRADIOL, LACTOSE MONOHYDRATE] (S - n/a - Drug withdrawn - [n/a - 1{DF} - Oral])		
EU-EC- 10011224127	11/01/2022	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
/			Professional				Sp. Scined			Recovered/Not Resolved - Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011224146	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	n/a])		
										Nausea (n/a -			

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										Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving			
:U-EC- 0011224379	11/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bone pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
				Arca						Lymph node pain (n/a - Recovering/Resolving	1,41)		
EU-EC-	11/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	- Other Medically Important Condition) Chest pain (19d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10011224415	11,01,101	Sportanious.	Professional	European Economic Area		Years	Specified	, rais		Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	not reported	
										Dehydration (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Headache (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Myocardial infarction (17d -			
										Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged			
										Hospitalisation, Other Medically Important Condition),			
										Nausea (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pericarditis (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (17d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Vomiting (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011224592	11/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (9d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011224612	11/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011224618	11/01/2022	Spontaneous	Non	Non European	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Illness (0d - Recovered/Resolved -), Loss of			
	11/01/2025	Charter	Haaliti -	Nov	Nakasa 2-U-	10.15	Net	Farre	N:	consciousness (0d - Recovered/Resolved - Other Medically Important Condition)	COMIDNAT/FOTTON	Net on the	105
EU-EC- 10011224818	11/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased activity (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	NOT reported	<u>ICSF</u>
										Decreased appetite (n/a - Unknown - Caused/Prolonged			

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										Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011225114	11/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Vaccination site pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)			
EU-EC- 10011225346	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Breast discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011225404	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebral palsy (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	11/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Condition aggravated (n/a - Recovering/Resolving - Other Medically Important Condition) Chest pain (n/a -	[TOZINAMERAN] (S - n/a -	[TOZINAMERAN] (C -	ICSR
10011225551	11/01/2022	Spontaneous		Economic	Not available	Years	Specified	ridic	No		Unknown - [n/a - n/a - n/a])	Immunisation - n/a - [n/a - n/a - n/a])	<u>ICSK</u>
	1.10.1000					12.17				Recovering/Resolving - Other Medically Important Condition)			1000
EU-EC- 10011225559	11/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011201662	10/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (n/a - Recovered/Resolved -), Injection site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										inflammation (n/a - Recovered/Resolved -), Injection site pain			
										(n/a - Recovered/Resolved -),			
EU-EC-	10/01/2022	Spontaneous		European	Not available	12-17	Not	Male	No	Pyrexia (5d - Recovered/Resolved -) Chest pain (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011201776			Professional	Economic Area	Not available	Years	Specified	Famala	No	Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10011201912	10/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a])	
										Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			

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										Condition), Presyncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU-EC-	10/01/2022	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011202001	10/01/2022	Sportaneous		European	Not available	Years	Specified	remale		(n/a - Not Recovered/Not Resolved - Disabling)	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	1001
EU-EC- 10011202135	10/01/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Unknown - Other Medically Important Condition), Migraine (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
U-EC-	10/01/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Recovered/Not Resolved - Other Medically Important Condition) Headache (n/a - Not	COMIRNATY [TOZINAMERAN]	[LATANOPROST] (C -	ICS
0011202156		·	Healthcare Professional	European Economic Area		Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Glaucoma - n/a - [n/a - n/a - n/a])	
										Unknown - Other Medically Important Condition), Inappropriate			
										schedule of product administration (n/a - Unknown - Other Medically Important Condition),			
J-EC-	10/01/2022	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	Off label use (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICS
0011202160	10/01/2022	Sportaneous	Healthcare Professional	European	Not available	Years	Specified	remale	No	upper (1d - Not Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	103
										Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling of body			
										temperature change (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not			
										Recovered/Not			

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										Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011202181	10/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011202904	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Exertional headache (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Pyrexia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011203111	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC-	10/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Polymenorrhoea (n/a - Recovering/Resolving -) Vaccination site pain	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011203169			Healthcare Professional	Economic Area		Years	Specified			(n/a - Recovering/Resolving -)	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011203311	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -), Insomnia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Muscle spasms (1d - Recovered/Resolved			
										-), Pain in extremity (1d - Recovered/Resolved			
										-), Pyrexia (1d - Recovered/Resolved			
EU-EC- 10011203764	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10011204087	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Confusional state (3d - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
										Cough (n/a - Unknown -),			
										Fatigue (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pityriasis rosea (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation),			
										Caused/Prolonged			

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										Syncope (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011204161	10/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011204678	10/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthropod bite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Purpura (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition),			
-11.50				_		10.17				Vasculitis (n/a - Unknown - Other Medically Important Condition)			1
EU-EC- 10011205268	10/01/2022	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Мане	No	Local reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011205332	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Electrocardiogram abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fibrin D dimer increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011205356	10/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSE
										Headache (1d - Recovered/Resolved -), Loss of			
										consciousness (1d - Recovered/Resolved -)			
EU-EC- 10011206556	10/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Lymphadenopathy (4d - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation)			

0.11.2022 EU-EC- 10011206608		Spontaneous	Healthcare	Economic	Not available	12-17 Years	Adolescent		No	g Report Influenza (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011206949	10/01/2022	Spontaneous	Professional Non Healthcare	Area European Economic	Not available	12-17 Years	Adolescent	Male	No	-) Myocarditis (n/a - Unknown -	- n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
			Professional	Area						Disabling), Pain in extremity (n/a - Unknown -	İntramuscular])		
EU-EC- 10011207888	10/01/2022	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Disabling) Abdominal pain upper (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
				Area						Dizziness (n/a - Recovering/Resolving -),	Unknown])		
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovering/Resolving			
EU-EC- 10011207906	10/01/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	-) Fatigue (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
10011207300			Professional			rears	Specifica			- Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Headache (31h - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011208007	10/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cutaneous vasculitis (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10011208113	10/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011208119	10/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (84d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[MAGNESIUM OXIDE] (C - Constipation - n/a - [n/a - n/a - Oral])	ICSF
										Bradypnoea (74d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Encephalitis (84d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Encephalitis autoimmune (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Encephalopathy (84d			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (85d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hyperthermia (84d - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation), Meningitis aseptic (84d -			

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											Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mononuclear cell count increased (84d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peritonitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (85d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Small intestinal perforation (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Small intestinal perforation (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (84d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
	-EC-	10/01/2022	Spontaneous			Not available	12-17	Adolescent	Female	No	Haematoma (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
	011208304	10/01/2022	Chontanoous	Professional		Not available	Years	Adoloscopt	Fomalo	No		(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICCD
100	-EC- 011208394		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Adolescent		No	- Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoacusis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMENATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		ICSR
	-EC- 011208397	10/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
	-EC- 011208511	10/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (0d - Recovered/Resolved - Disabling), Asthenia (n/a - Unknown - Disabling), Malaise (0d - Recovered/Resolved - Disabling), Myalgia (0d - Recovered/Resolved - Disabling), Palpitations (0d - Recovered/Resolved - Disabling)	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	-EC- 011208583	10/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bedridden (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cachexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Caused/Prolonged			
										Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Impaired work ability (9wk - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Influenza like illness (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011208838	10/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Not Resolved -), Wrong schedule (n/a - Recovered/Resolved			
EU-EC- 10011209056	10/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypertension (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pruritus (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved			
										-), Vaccination site urticaria (n/a - Recovered/Resolved -)			
EU-EC- 10011209082	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]	Not reported	ICSR
EU-EC- 10011209228	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011209280	10/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011209342		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthropod bite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Eczema (n/a - Unknown - Other Medically Important			

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										Condition), Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Purpura (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a -			
										Unknown - Other Medically Important Condition)			
EU-EC- 10011209411	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunisation (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Tonic convulsion (n/a			
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011209413		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Adolescent		No	Lymphadenitis (n/a - Recovering/Resolving -)	Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10011209465	10/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011209761	10/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye swelling (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Hemiparesis (13d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Monoparesis (13d - Unknown -)			
EU-EC- 10011209778	10/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Hypersensitivity (n/a - Unknown - Other Medically Important Condition),			
										Pruritus (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011209937	10/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011209961	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal distension (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pruritus (n/a - Unknown - Other Medically Important Condition),			

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										Rash (n/a - Unknown - Other Medically Important Condition),			
										Swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011209985	10/01/2022	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	ICSF
EU-EC- 10011210011	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011210214	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011210370	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Heavy menstrual bleeding (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011210440	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										(n/a - Unknown -), Dyspnoea (n/a - Recovering/Resolving			
EU-EC- 10011210477	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011210515	10/01/2022	Spontaneous		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	ICSF
EU-EC-	10/01/2022	Spontaneous		European	Not available	12-17	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -) Asthenia (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011210530			Healthcare Professional	Economic Area		Years				Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Rash (n/a - Not Recovered/Not Resolved -),			
EU-EC-	10/01/2022	Spontaneous	Lionithean	Furancan	Not available	12-17	Adolescent	Formula	No	Vomiting (n/a - Not Recovered/Not Resolved -) Abdominal pain (1d -	COMIDNATY ITOZINAMEDANI	Not reported	ICCD
10011210667	10/01/2022	Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent	remale	NO	Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011211121	10/01/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (7d - Recovered/Resolved -),			
										Nasopharyngitis (7d - Recovered/Resolved -)			
EU-EC- 10011211799	10/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (9d - Recovered/Resolved With Sequelae - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[FERROUS SULFATE] (C - Anaemia - n/a - [n/a - n/a - n/a])	ICSR
										Malaise (n/a - Unknown - Other			

										Medically Important Condition)			
EU-EC- 10011211884	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (30d - Recovered/Resolved -), Urticaria (30d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC-	10/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Recovered/Resolved -) Altered state of	COMIRNATY [TOZINAMERAN]	Not reported	ICS
0011211974	10/01/2022	эропшнеоиз	Professional	European Economic Area	Not available	Years	Specified	Piaic		consciousness (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	100
										Fall (n/a - Unknown - Other Medically Important Condition),			
										Gaze palsy (n/a - Unknown - Other Medically Important Condition),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Mental impairment (n/a - Unknown - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Respiratory arrest (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011212244	10/01/2022	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
				Economic Area						Fall (n/a - Recovering/Resolving -),	Not applicable - [n/a - n/a - Intramuscular])		
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Presyncope (n/a - Recovering/Resolving			
EU-EC- 10011212970	10/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
10011212370				Area		lears				(5d - Recovered/Resolved -)	Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10011212972	10/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICS
										Headache (1d - Recovered/Resolved -),	Ind and scular Jy		
										Malaise (1d - Recovered/Resolved -),			
										Vomiting (1d - Recovered/Resolved			
EU-EC- 10011212980	10/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (2min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011213478	10/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Eye movement disorder (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Fall (0d - Recovered/Resolved -),			
										Muscle rigidity (0d - Recovered/Resolved -),			

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										Seizure (0d - Recovered/Resolved - Other Medically Important Condition), Tonic convulsion (n/a - Recovered/Resolved - Other Medically Important Condition), Tremor (0d - Recovered/Resolved			
EU-EC- 10011213650	10/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
10011213030			Professional			rears	Specificu			Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (2d -	Not applicable - [n/a - 1{DF} - n/a])		
										Recovered/Resolved -), Headache (n/a - Not Recovered/Not			
										Resolved -), Malaise (2d - Recovered/Resolved -),			
										Myalgia (n/a - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -)			
EU-EC- 10011200278	09/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
	20 (01 (2022					12.17				Vaccination failure (n/a - Unknown - Other Medically Important Condition)			1000
EU-EC- 10011201250	09/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011201338	09/01/2022	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										-), Rash (n/a - Recovering/Resolving -)			
EU-EC- 10011195731	08/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Lymphadenopathy (n/a - Recovered/Resolved -),			
										Malaise (n/a - Recovered/Resolved -),			
										Migraine (n/a - Recovered/Resolved -), Myalgia (n/a -			
										Recovered/Resolved -), Pyrexia (n/a -			
EU-EC- 10011196092	08/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Eye pruritus (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
10011130032			Professional			icais	эрсинеи			-), Ocular hyperaemia (n/a - Recovering/Resolving	(3 - COVID-19 illinitinisation - n/a - [n/a3mL - Intramuscular])		
										-), Swelling (n/a - Recovering/Resolving -)			
EU-EC- 10011196093	08/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Recovered/Not Resolved -)			

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EU-EC- 10011197571	08/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Injection site 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- 100111197592	08/01/2022	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 (6d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Recovered/Resolved -), Malaise (n/a - Not Recovered/Not			
										Resolved -), Myalgia (6d - Recovered/Resolved -),			
										Nausea (n/a - Recovering/Resolving -)			
EU-EC- 10011199140	08/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphonia (3d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC-	08/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Headache (3d - Not Recovered/Not Resolved -) Arthralgia (3d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011199296	00/01/2022	эропшисов		Economic	Not available	Years	Specified	remaie		Recovered/Resolved -), Chills (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	1001
										Recovered/Resolved -), Fatigue (11d -			
										Recovered/Resolved -), Headache (4d - Recovered/Resolved			
										-), Malaise (11d - Recovered/Resolved			
										-), Myalgia (3d - Recovered/Resolved			
										Nausea (n/a - Recovering/Resolving			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10011187576	07/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Epstein-Barr virus infection (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- 10011187577	07/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10011188381	07/01/2022	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 - 1{DF} - n/a])	Not reported	ICSF
										Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10011188794	07/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Aphasia (1mo - Recovered/Resolved - Disabling), Pyrexia (3d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011188808	07/01/2022	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	- Disabling) Bell's palsy (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
				Area						Caused/Prolonged Hospitalisation, Other Medically Important Condition)	n/a])		
EU-EC- 10011188816	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011188856	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Organ failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged			
EU-EC-	07/01/2022	Spontaneous	Non	Europoon	Not available	12-17	Not	Female	No	Hospitalisation)	COMIDNATY [TOZINAMEDAN]	Not reported	ICCD
10011189702	07/01/2022	Spontaneous		European Economic Area	NOL AVAIIADIE	Years	Specified	remale	INO	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Amenorrhoea (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Injection site haematoma (4d - Recovered/Resolved -),			
										Injection site inflammation (4d - Recovered/Resolved -),			
										Injection site pain (4d - Recovered/Resolved -),			
										Injection site swelling (4d - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (3d - Recovered/Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (3d - Recovered/Resolved -)			
EU-EC- 10011189839	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chronic spontaneous urticaria (95d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011189943	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Death (n/a - Fatal - Results in Death)			
EU-EC- 10011189947	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU EO	07/04/2022					10.17				Tremor (n/a - Not Recovered/Not Resolved -)			1000
EU-EC- 10011189956	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Herpes zoster (n/a - Recovering/Resolving -), Rash (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -)			
EU-EC- 10011190097	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Disabling),			
										Malaise (n/a - Recovering/Resolving - Disabling),			
										Nausea (n/a - Recovering/Resolving - Disabling),			
										Pyrexia (n/a - Recovering/Resolving - Disabling),			
EU-EC-	07/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Vomiting (n/a - Recovering/Resolving - Disabling) Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011190309	,,,,		Professional			Years	Specified				(S - COVID-19 immunisation -		

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				Area						- Caused/Prolonged Hospitalisation, Other Medically Important Condition),	n/a - [n/a3mL - Intramuscular])		
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011190318	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Head injury (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	07/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition) Erythema nodosum	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011190464			Healthcare Professional	Economic Area		Years				(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tonsillitis (n/a -	(S - n/a - n/a - [1d - n/a - Intramuscular])	·	
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011190515	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										bleeding (n/a - Not Recovered/Not Resolved -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011190889	07/01/2022	Spontaneous		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 - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011190905	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011191651	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 100111191781	07/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation, Ill-defined disorder - Not	LEVETIRACETAM [LEVETIRACETAM] (C - III-defined disorder - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										Photosensitivity		MIDAZOLAM	

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										reaction (0d - Recovered/Resolved - Other Medically Important Condition), Seizure (3d -		[MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a]),	
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a]),	
										Status epilepticus (n/a - Unknown - Caused/Prolonged Hospitalisation,		[CLOBAZAM] (C - III- defined disorder - n/a - [n/a - n/a - Oral]),	
										Other Medically Important Condition), Vomiting (1d -		[ETHOSUXIMIDE] (C - Ill-defined disorder - n/a - [n/a - 5mL - n/a - More in ICSR]),	
										Recovered/Resolved - Other Medically Important Condition)		[LAMOTRIGINE] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a]),	
												[MEDIUM-CHAIN TRIGLYCERIDES] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a]),	
												[PARAFFIN, LIGHT LIQUID, PARAFFIN, LIGHT LIQUID, PARAFFIN WHITE SOFT] (C - III-defined disorder - n/a - [n/a - n/a - n/a]),	
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - III- defined disorder - n/a - [n/a - n/a - n/a]),	
												[SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Ill-defined disorder - n/a - [n/a - n/a -	
EU-EC-	07/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Influenza like illness	COMIRNATY [TOZINAMERAN]	n/a]) Not reported	ICSR
10011191981				Economic		Years				(2d - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Pyrexia (2d - Not Recovered/Not Resolved -)			
EU-EC- 10011191985	07/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Injection site reaction (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Injection site swelling (4d - Recovered/Resolved -),			
										Peripheral swelling (4d - Recovered/Resolved -)			
EU-EC- 10011191998		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011192017	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 100111192136	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 100111192150	07/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011192165	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myalgia (n/a - Not			

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										Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other			
										Medically Important Condition)			
EU-EC- 10011192173	07/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011192179	07/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011192180	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Vaccination site pain (0d - Recovered/Resolved -)			
EU-EC- 10011192513	07/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011192717	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (2h - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Disturbance in attention (n/a - Unknown -),			
										Dyspnoea (n/a - Unknown -), Hyperhidrosis (1h -			
										Recovered/Resolved -), Hyperventilation (n/a - Unknown -),			
										Hypotension (2h - Recovered/Resolved -),			
										Pallor (n/a - Unknown -),			
										Vision blurred (n/a - Unknown -)			
EU-EC- 10011192742	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast enlargement (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL, LACTOSE, LACTOSE HYDROUS, LACTOSE	ICSR
										Chills (4h - Recovered/Resolved -),		MONOHYDRATE] (C - Dysmenorrhoea - n/a - [n/a - n/a - Oral]),	
										Fatigue (n/a - Unknown -), Loss of		[LORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral])	
										consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Lymphadenopathy (n/a - Recovered/Resolved -),			
										Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10011192751		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC- 10011192854	07/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011192869	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011192885	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ear infection (n/a - Recovering/Resolving -), Ear swelling (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown -), Haemorrhage (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Illness (n/a - Unknown -),			
										Tympanic membrane perforation (n/a - Recovering/Resolving -)			
EU-EC- 10011192887	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Unknown -),			
										Feeling abnormal (n/a - Unknown -),			
										Headache (n/a - Unknown -), Immune system			
										disorder (n/a - Unknown -),			
										Swelling (n/a - Unknown -),			
										Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU 50	07/04/2022				No.	42.47		- 1		Weight decreased (n/a - Unknown -)	COMMUNICATION AND AND AND AND AND AND AND AND AND AN		1000
EU-EC- 10011193323	07/01/2022	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Female	No	Neuromyelitis optica spectrum disorder (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193362	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Tonic convulsion (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011193412		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10011193463	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tension headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193514	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193615	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193658	07/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 2{DF} - Intramuscular])	Not reported	ICSR
										Dysmenorrhoea (n/a			
										Recovering/Resolving -),			
		I			I	1		I	1	Pyrexia (n/a -	l	l	

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										Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving			
										-), Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10011193713	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193728	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193729	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011193738	07/01/2022	Spontaneous	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- 10011193976	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Unknown -),			
										Headache (n/a - Recovering/Resolving -),			
										Influenza (n/a - Recovering/Resolving -),			
										Injection site pain (1d - Unknown -),			
										Lymphadenopathy (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011194185	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011194888	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011195593	07/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Menstrual disorder		Not reported	ICSR
										(n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011196405	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved -),			
EU-EC- 10011196517	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Productive cough (n/a - Unknown -) Arthralgia (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	[MELATONIN] (C - n/a - n/a - [n/a - n/a	ICSR
										Disabling), Axillary pain (n/a - Not Recovered/Not Resolved - Disabling),	Intramuscular])	- n/a]), [DROSPIRENONE, ETHINYLESTRADIOL, LACTOSE ANHYDROUS,	
										Chest pain (n/a - Not Recovered/Not Resolved - Disabling),		LACTOSE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -			
										Disabling), Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011197139	07/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
ı										Leukocytosis (n/a - Unknown - Life			

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										Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Neutrophilia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011197221	07/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011197391		Spontaneous	Professional		Not available	12-17 Years	Adolescent	Female	No	Resolved -) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011174824		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Cough (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Face oedema (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a3mL - Intramuscular])	Not reported	ICSR
										With Sequelae - Caused/Prolonged Hospitalisation), Swelling (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Urticaria (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved			
										With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10011175152	06/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Dysmenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperpyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Injection site pain (n/a - Recovered/Resolved Other Medically Important Condition),			
EU-EC-	06/01/2022	Coopton	Non	Europa	Not available	12.17	Not	Mala	No	Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIDNATY ITOZINAMEDANI	[CHI ODDI ITALAATAIT	ICCD
10011175153		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition),	Not applicable - [n/a - 1{DF} - Intramuscular])	[CHLORPHENAMINE MALEATE, SODIUM CROMOGLICATE] (C - Conjunctivitis allergic - n/a - [n/a - n/a - n/a])	<u>ICSR</u>

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										Hyperpyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Injection site pain (n/a - Recovered/Resolved - Other Medically Important			
										Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 100111751	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Hallucination, auditory (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (0d - Recovered/Resolved - Other Medically Important Condition),			
EU-EC- 100111752		Spontaneous		European Economic	Not available	12-17 Years	Not	Male	No	Tachycardia (0d - Recovered/Resolved - Other Medically Important Condition) Erythema (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis -	Not reported	<u>ICSR</u>
100111752	73		Professional			rears	Specified			Lymphadenopathy (n/a - Recovered/Resolved	(S - COVID-19 propriylaxis - Not applicable - [n/a - 1{DF} - Intramuscular])		
										-), Pruritus (n/a - Recovered/Resolved -), Tachycardia (n/a -			
EU-EC-	06/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Not	Female	No	Recovered/Resolved -) Hyperpyrexia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
100111752		ľ	Professional			Years	Specified			Not Recovered/Not Resolved -), Tremor (n/a - Not	(S - n/a - n/a - [n/a - n/a - Intramuscular])	·	
										Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not			
EU-EC- 100111753		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Arthralgia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chills (1d - Recovered/Resolved -),			
										Fatigue (3d - Recovered/Resolved -),			
										Headache (3d - Recovered/Resolved -),			
										Malaise (3d - Recovered/Resolved -),			
										Myalgia (2d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 100111760		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bundle branch block right (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - 1,8mL - Intramuscular])	Not reported	ICSR
										Disease recurrence (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Overdose (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 100111760		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>

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										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Electrocardiogram ST segment elevation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011176068	06/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011177204	06/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Acne - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Hypokinesia (n/a - Unknown - Other Medically Important Condition),			
										Insomnia (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011177206	06/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011177280	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Malaise (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Disabling,			

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											Other Medically Important Condition),			
											Ocular icterus (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Palpitations (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Pericarditis (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Skin discolouration (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Syncope (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Tachycardia (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Yellow skin (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
	EU-EC- 10011177325	06/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Depressed level of consciousness (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
											Inappropriate schedule of product administration (n/a - Unknown - Life Threatening, Other Medically Important Condition),			
											Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),			
											Neurogenic shock (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
											Pallor (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
											Pulse abnormal (n/a - Recovered/Resolved - Life Threatening, Other Medically Important			
											Condition), Pyrexia (n/a - Recovered/Resolved - Life Threatening, Other Medically			
	EU-EC- 10011177336	06/01/2022	Spontaneous	Healthcare	European	Not available	12-17 Years	Not Specified	Not Specified	No	Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				Professional	Economic Area						Condition), Pain (n/a - Unknown	Not applicable - [1d - n/a - n/a])		
											- Other Medically Important Condition),			
											Peripheral swelling (n/a - Unknown - Other Medically Important			
	1			l	I		I	I			I			- 1

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										Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a -			
										Unknown - Other Medically Important Condition), Rash erythematous (n/a - Unknown -			
EU-EC-	06/01/2022	Spontaneous	Hoalthcaro	Non	Not available	12-17	Not	Female	No	Other Medically Important Condition) Diplopia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011177374	00/01/2022	Sportaneous		European Economic Area	Not available	Years	Specified	remaie	NO	Unknown - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSK</u>
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Ocular discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011177394	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amnesia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a -	<u>ICSR</u>
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),		[n/a - n/a - n/a])	
										Seizure (1d - Recovered/Resolved - Other Medically Important Condition),			
										Tremor (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011177418	06/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011177461	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	Not reported	ICSR
										Chest pain (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011177524	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011177841	06/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (0d - Recovered/Resolved -), Fatique (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Recovering/Resolving -), Headache (0d -			
										Recovered/Resolved -), Lip blister (n/a - Recovering/Resolving			
										-), Lip swelling (n/a - Recovering/Resolving			
										-), Malaise (1d - Recovered/Resolved			
										Nausea (0d - Recovered/Resolved			

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										Oral herpes (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovered/Resolved			
J-EC- 0011178178	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Back pain (n/a - Unknown -),	, ,		
										Dizziness (n/a - Unknown -),			
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),			
										Dysstasia (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Heavy menstrual bleeding (n/a - Unknown -),			
										Muscle spasms (n/a - Unknown -),			
										Tremor (n/a - Unknown -),			
J-EC-	06/01/2022	Cnontangous	Non	Non	Not available	12-17	Not	Famala		Vomiting (n/a - Unknown -)	COMIDNIATY (TOZINIAMEDANI)	Not reported	ICC
011178336	06/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	Years	Specified	Female		Feeling hot (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Gait inability (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Not			
										Recovered/Not Resolved - Other Medically Important			
-EC- 011178398	06/01/2022	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Condition) Heart rate irregular (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation	Not reported	ICS
			Professional	Economic Area						Other Medically Important Condition),	Not applicable - [n/a - n/a - n/a])		
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other			
										Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
J-EC- 011178402	06/01/2022	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Immunisation (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
			, , , , , , , , , , , , , , , , , , , ,	Area						Hospitalisation, Other Medically Important Condition),	n/a])		
										Muscle spasms (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation, Other Medically			
J-EC- 0011178404	06/01/2022	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Brain injury (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Professional	Economic Area						Resolved - Caused/Prolonged Hospitalisation, Other Medically	Not applicable - [1d - n/a - n/a])		
										Important Condition),			
										Coma (3d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Concentric sclerosis (n/a - Not Recovered/Not Resolved -			
						1	1	1	I			I	
										Disabling), Dizziness (n/a -			

Professional Economic Area Professional Economic Area Years Specified Vears Specified	
Unknown -), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Nospitalisation) Unknown -), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Nospitalisation) Unportant - Condition), Product administered at inappropriate site (n/a - Unknown -), Vomiting (n/a - Recovered/Resolved With Sequetae - Caused/Prolonged in the Recovered R	
Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Interpretation) Healthcare Non Professional Economic Area	
Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product administered at Imporportate site (m/a - Unknown -), Vorniting (m/a Recovered/Resolved Hospitalisation, Other Medically Important Condition), Product administered at Imporportate site (m/a - Unknown -), Vorniting (m/a Recovered/Resolved Hospitalisation, Other Medically Important Condition), Product administered at Important Condition, Product administered at Important Condition, Professional European New Years Professional European New	
Condition Product administered at inappropriate site (n/a - Unknown -), Vomiting (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Not available 12-17 Not Years Specified No Epistasis (n/a - Unknown -), Comiron Not available Professional Professional Not available No Professional No Professional No Professional Not available No Professional Not available No Professional No Professional No Professional Not available Not a	
Product administered at inappropriate site (n/a - Unknown -), Vomiting (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition) EU-EC- 10011178514 Description of the Medically Important Condition of the Medicall	
EU-EC- 10011178514 Professional EU-EC- 10011178570 Professional EU-EC- 10011178570 Professional EU-EC- 10011178570 Professional Eu-Eu- Not available Professional Eu- Professiona	
EU-EC- 10011178514 Companies Companie	
EU-EC- 1001/178514 Description Professional	
EU-EC- 06/01/2022 Spontaneous Healthcare 10011178570 Economic Area Feeling hot (n/a - Unknown -), Feeling hot (n/a - Unknown -), Feeling hot (n/a - Unknown -), Interchange of vaccine products (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Obstructive airways disorder (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -), Off label use (n/a - Inknown -), Off label us	[TOZINAMERAN] Not reported ICSR
Comparison Com	le - [n/a - n/a -
Vaccine products (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Other Medically Important Condition), Obstructive airways disorder (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -)	
Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition), Obstructive airways disorder (n/a - Unknown -), Off label use (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown -)	
EU-EC- 10011178570 Spontaneous Healthcare Professional European Eur	
EU-EC- 06/01/2022 Spontaneous Healthcare Non Not available 12-17 Not Female No Decreased appetite (n/a - Unknown -) Frofessional European Professional European (No Specified Vears Specified No Decreased appetite (No - Unknown -) (S - COVI	
EU-EC- 06/01/2022 Spontaneous Healthcare Non Not available 12-17 Not Female No Decreased appetite (n/a - Unknown -) Professional European Vears Specified (n/a - Unknown -)	
10011178570 Professional European Years Specified (n/a - Unknown - (S - COVI	
Economic Caused/Prolonged Not applic Hospitalisation), n/a])	[TOZINAMERAN] 19 immunisation - le - [1d - n/a -
Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	
Fatigue (n/a - Unknown - Caused/Prolonged	
Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged	
Hospitalisation), Malaise (n/a -	
Unknown - Caused/Prolonged Hospitalisation),	
Pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	
Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	
White blood cell count increased (n/a - Unknown - Caused/Prolonged	
Hospitalisation)	[TOZINAMERAN] Not reported ICSR
Professional Professional Real	9 IIIIIIIIIII84001 - le - [1d - n/a -
Chest pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation,	
Other Medically Important Condition),	
Dizziness postural (n/a - Not Recovered/Not Resolved -	

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											Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Palpitations (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10011180673	06/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown -			
											Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown - Caused/Prolonged			
											Hospitalisation), Ventricular extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Ventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10011180698	06/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Hyperventilation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hopticalisation, Other Medically Important Condition),			
											Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Weight decreased (n/a - Not Recovered/Not Resolved -			

ı	.11.2022							1			Other Medically			
											Important Condition)			
	EU-EC- 10011180703	06/01/2022	Spontaneous	Healthcare Professional	European	Not available	12 - 17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Breath sounds (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Circulatory collapse (n/a - Fatal - Results in Death, Caused/Prolonged			
											Hospitalisation), Cyanosis (n/a - Fatal - Results in Death, Caused/Prolonged			
											Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged			
											Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged			
											Hospitalisation), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged			
1	EU-EC- 10011180726	06/01/2022	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Haematuria (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
					Aled						IgA nephropathy (n/a - Unknown - Other Medically Important Condition),	intrantuscular j)		
											Proteinuria (n/a - Unknown -), Pyrexia (n/a - Not			
	TH EC	06/01/2022	Casatanasus	Non	New	Not available	12.17	Net	Mala	Na	Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	KEDDDA	TCCD
	EU-EC- 10011180756	06/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Loss of personal independence in daily activities (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
											Myoclonic epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged		[CLOBAZAM] (C - n/a - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C -	
											Hospitalisation, Other Medically Important Condition),		n/a - n/a - [n/a - n/a - n/a])	
											Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically			
	EU-EC- 10011181009	06/01/2022	Spontaneous	Healthcare Professional	European	Not available		Not Specified	Male	No	Important Condition) Muscle twitching (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	EU-EC- 10011181058	06/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition),			

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										Pain in extremity (4d - Recovered/Resolved - Other Medically			
EU-EC- 10011181480	06/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011181698	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Abnormal loss of weight (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Arthralgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Arthritis reactive (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Colitis ulcerative (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Myalgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Rectal haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10011181745	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011181785	06/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1h - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011182175	06/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Delirium (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC-	06/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Feeling hot (n/a - Unknown -) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011182409	00,01,2022	Sportaneous	Professional			Years	Specified	, ide		Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	not reported	
EU EC	00/04/2022	Constant	Nam	Name	Nat and table	12.17	Note	FI.	NI-	Other Medically Important Condition)	COMPAND (TOTALIAMEDAN)	Networked	100
EU-EC- 10011182523	UO/U1/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Autoimmune disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	invol reported	ICS
										Pyoderma gangrenosum (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation,			

			I	I	I	ı	1			Other Medically	I	I	ı
EU-EC-	06/01/2022	Spontaneous	Hooltheare	Non	Not available	12-17	Not	Male	No	Important Condition)	COMIDNIATY [TOZINIAMEDAN]	Not reported	ICSR
10011182529	06/01/2022	spontaneous	Professional	Non European Economic Area	Not available	Years	Specified	Male	No	Axillary pain (13d - Recovered/Resolved -), Blood lactate dehydrogenase	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										increased (n/a - Unknown -), Chest pain (15d -			
										Recovered/Resolved -), Electrocardiogram QRS complex			
										prolonged (13d - Recovered/Resolved - Other Medically Important Condition),			
										Lymph node pain (14d - Recovered/Resolved -),			
										Lymphadenopathy (13d - Recovered/Resolved -),			
										Pain in extremity (13d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -),			
										Wolff-Parkinson- White syndrome (13d - Recovered/Resolved			
EU-EC-	06/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	- Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011182600	00/01/2022	3portaneous	Professional		Not available	Years	Adolescent	Male	NO	Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSK</u>
										Pyrexia (n/a - Recovered/Resolved -), Transaminases			
										increased (n/a - Recovered/Resolved -)			
10011182602		Spontaneous	Healthcare Professional	Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10011182632	06/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Alopecia (n/a - Recovered/Resolved -), Pruritus (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Not Resolved -), Rash macular (n/a -			
EU-EC-	06/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Not Recovered/Not Resolved -) Guillain-Barre	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011182746	00/01/2022	Sportaneous	Professional		Not available	Years	Adolescent	raic		syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSIX
EU-EC- 10011182788	06/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adult	Female	No	Abdominal pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Angioedema (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Face oedema (1d - Recovered/Resolved -),			
										Rash (1d - Recovered/Resolved -),			
										Throat irritation (1d - Recovered/Resolved -)			
10011182882		Spontaneous	Professional		Not available	12-17 Years	Adolescent		No	Pericarditis (4wk - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		ICSR
EU-EC- 10011182973	06/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening, Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

Class Control Contro	٠.										_1011116	, report			
Condition Cond												Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Unknown - Other			
DATE Part DATE												Condition), Dyspnoea (n/a - Recovered/Resolved			
Main												Pallor (n/a - Recovered/Resolved			
EU-C- 10011103200 Col. 17.2122 Sportnerocca Manual Processions Processio												Tachypnoea (n/a -			
BLACE INC. 183306 BLACE			06/01/2022	Spontaneous	Professional	European Economic	Not available			Female	No	Dizziness (n/a - Unknown - Caused/Prolonged	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
Button Committee Committ												Unknown - Caused/Prolonged			
University Cases of Protection Cases o												Unknown - Caused/Prolonged			
E1-EC 05/01/2022 Spontaneous No. Not shalled 23-17 Not Not specified Not spe												Unknown - Caused/Prolonged			
ELI-EC- 10011183300 (%-01/2022 Sportlamenus Nem Healthcare Professional Science Professiona												Unknown - Caused/Prolonged			
ELHEC. 10011183301 06/01/2022 Spontaneous Non Non Healthcare European Professional Economic Avea Not reported Interpretational Economic Professional Economic Avea Not reported Interpretational Economic Professional Economic Avea Not reported Interpretational Economic Professional Economic Notation Individual Economic Professional Economic Notation Individual Economic Individual Economic Individual Individual Economic Individual Individ												- Caused/Prolonged Hospitalisation),			
ELEC. 10011183301 06/01/2022 Spontaneous Mon Healthcare European Professional Area Not available 2:2-17 Not Continue Professional Area Not available 2:2-17 Not Specified Male Not Inspiration (n/a administration (n/a administra												Unknown - Caused/Prolonged Hospitalisation),			
EU-EC- 10011183301 20 20 20 20 20 20 20												Unknown - Caused/Prolonged			
EU-EC- 100/1/2022 Spontaneous Non Healthcare Economic Professional Area Are			06/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available			Male	No	Inappropriate schedule of product administration (n/a -	[TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	<u>ICSR</u>
EU-EC- 10011183568 O6/01/2022 Spontaneous Non Healthcare Economic Professional Area EU-FC- 10011183568 O6/01/2022 Spontaneous Non Healthcare Economic Professional Area European Healthcare Economic Professional Area Not Specified Female No Dizziness postural (Not - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Unknown - Life Threatening, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pallor (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a - Not Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a - Not Seizure (2min - Unknown - Life Threatening, Other Seizure (2min - Unknown - Unknown - Life Threatening, Other Seizure (2min - Unknown - Unk												independence in daily activities (n/a - Recovered/Resolved - Other Medically Important			
EU-EC- 10011183568 O6/01/2022 Spontaneous Non Healthcare Professional Healthcare Professional State Profess												- ' '			
Healthcare Professional Area Healthcare Professional Area Years Specified Years Specified Years Specified (n/a - Not Recovered/Not Resolved -), Feeling cold (n/a - Unknown - Life Threatening, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (Zmin - Unknown - Life Threatening, Other Medically Important Condition), Seizure (Zmin - Unknown - Life Threatening, Other Medically Important Condition), Seizure (Zmin - Unknown - Life Threatening, Other Medically Important Condition), Seizure (Zmin - Unknown - Life Threatening, Other Medically Important Condition), Seizure (Zmin - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a -		EU-EC-	06/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	- Other Medically Important Condition)	COMIDNATY [TOTNIAMED AN]	Not reported	ICCD.
Unknown - Life Threatening, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a -			00/01/2022	Spontaneous	Healthcare	Economic	Not available			remale	NO	(n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSK</u>
Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a -												Unknown - Life Threatening, Other Medically Important			
Unknown - Life Threatening, Other Medically Important Condition), Seizure (2min - Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a -												Recovered/Not Resolved - Other Medically Important			
Unknown - Life Threatening, Other Medically Important Condition), Swelling face (n/a -												Unknown - Life Threatening, Other Medically Important			
Swelling face (n/a -												Unknown - Life Threatening, Other Medically Important			
												Swelling face (n/a -			

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										Threatening, Other Medically Important Condition),			
										Syncope (n/a - Unknown - Life Threatening, Other Medically Important Condition)			
EU-EC- 10011183805	06/01/2022	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	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011183992	06/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Oral pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sleep disorder (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011184079	06/01/2022	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	ICSR
				_						Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011184082	06/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	06/01/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011184225	00/01/2022	Sportarieous		Economic	Nut available	Years	Adolescent	remale	No	-)	(S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA	Not reported	<u>ICSK</u>
											(CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011184311	06/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (1d - Recovered/Resolved -), Vomiting (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC-	06/01/2022	Spontaneous		European	Not available	12-17	Not	Male	No	Recovered/Resolved -) Dermatitis bullous	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
10011184586			Healthcare Professional	Economic Area		Years	Specified			(n/a - Not Recovered/Not Resolved -), Fatigue (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Recovering/Resolving -), Malaise (n/a - Recovering/Resolving			
										-), Pyrexia (2d - Recovered/Resolved			
EU-EC- 10011184829	06/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood glucose decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[COLECALCIFEROL] (C - Supplementation therapy - n/a - [n/a - n/a - Oral])	ICSR
										Hypotension (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
										Skin discolouration (n/a - Recovered/Resolved - Life Threatening, Other Medically			
EU-EC-	06/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Important Condition) Blood pressure	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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CHACLE December Characteristics Characte	10011184851			Professional	Economic		Years	Specified			Recovered/Resolved - Other Medically Important Condition),	Not applicable - [n/a - n/a -		
Performance	ELLEC	06/01/2022	Chantanaous	Hoaltheave	Non	Not poilable	12.17	Not	Famala	No	consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIDNATY (TOZINAMEDANI)	Not reported	ICCD
Purpose Purp		06/01/2022	Spontaneous		European Economic	Not available			remale	INO	Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
Hi-FC- George G											Dizziness (n/a - Unknown - Caused/Prolonged			
Caused Perlonged											Unknown - Caused/Prolonged Hospitalisation),			
E1-EC- O5/01/2022 Sportaneous Non- Healthcare Non- Healthcare Non- Healthcare Non- Healthcare Non- Non											Caused/Prolonged Hospitalisation), Headache (n/a -			
EU-EC- 10011185142 20 20 20 20 20 20 20											Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -			
Healthcare Professional Profes											Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged			
EU-EC- 1001/163354 Professional Professiona		06/01/2022	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	Recovered/Resolved -), Pyrexia (32d - Recovered/Resolved	(S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011183488		06/01/2022	Spontaneous		European Economic	Not available			Male	No	Myocarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011162834 Professional Recovering/Resolving Caused/Protonged Caused/	FILEC	05/01/2022	Constant	New	5,,,,,,,,,	New year Stability	12.17	Adelessan	Famala	No	Troponin increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMPANY (TO TANASTRAL)	Not to a stand	ICCD
Professional Economic Area Professional Economic Area Professional Professional Area Professional Professional Area Professional Professional Professional Area Professional	10011185488	06/01/2022	Spontaneous	Healthcare	Economic	NOL available		Adojesceni	генаје	INO	Recovering/Resolving - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		ICSR
EU-EC- 10011162834 D5/01/2022 Spontaneous Healthcare 10011162834 D5/01/2022 Spontaneous Healthcare 10011162834 D5/01/2022 Spontaneous Healthcare 10011163059 D5/01/2022 Spontaneous Non 10011163059 D6/01/2022 Spontaneous Non 10011163059 D6/01		05/01/2022	Spontaneous		Economic	Not available		Adolescent	Male	No	Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
Professional Prof											(n/a - Unknown - Other Medically			
EU-EC- 10011163059 O5/01/2022 Spontaneous Non Healthcare Professional Recommic Area Not available 12-17 Years Not Specified Male Specified Male No Abdominal pain upper (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -)		05/01/2022	Spontaneous		Economic	Not available			Female	No	consciousness (n/a - Recovering/Resolving - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
Healthcare Professional Profess	EU-EC-	05/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Recovering/Resolving - Other Medically Important Condition)		Not reported	ICSR
-), Headache (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved	10011163059			Healthcare	Economic		Years	Specified			upper (3d - Recovered/Resolved -), Fatigue (3d -	(S - COVID-19 immunisation - n/a - [n/a3mL -	·	
Nausea (3d - Recovered/Resolved											-), Headache (3d - Recovered/Resolved			
											Nausea (3d - Recovered/Resolved			
Pain (3d - Recovered/Resolved -),											Recovered/Resolved			

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										Vertigo (3d - Recovered/Resolved			
EU-EC- 100111163176	05/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Recovered/R	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	IC
										Resolved -), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011163228	05/01/2022	Spontaneous		European Economic Area	Not available		Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Cough (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	IC
EU-EC- 10011163992	05/01/2022	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Blood pressure increased (24min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
EU-EC- 10011163994	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Epistaxis (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
				Area						Petechiae (n/a - Not Recovered/Not Resolved -),	n/a])		
										Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011164002	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
										Decreased appetite			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011164040	05/01/2022	Spontaneous	Healthcare Professional	Non 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 applicable - [1d - n/a - Intramuscular])	Not reported	IC
										Dry mouth (n/a - Not Recovered/Not Resolved -),	-		
										Sleep disorder (n/a - Not Recovered/Not Resolved -),			
										Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011164048	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Dysuria (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
				Area						Hypoaesthesia (n/a - Unknown -),	Intramuscular])		
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
EU FC	05/04/2022	Cuant	Hoolet-	Non	Materia de la	12.17	Not	Mal-	NI-	Pyrexia (n/a - Recovered/Resolved -)	COMIDNATY	Not you	1,5
EU-EC- 10011164049	ub/U1/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	пиот герогтеа	<u>IC</u>
EU-EC- 10011164051	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
										consciousness (n/a - Recovered/Resolved			

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										- Other Medically Important Condition)			
:U-EC- .0011164058	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Dizziness (50min - Recovered/Resolved -), Syncope (50min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0011164090	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged			
:U-EC- 0011164101	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
U-EC- 0011164137	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Haematemesis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
U-EC- 0011164463	05/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abscess (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICS
										COVID-19 immunisation (n/a - Not Recovered/Not Resolved -)			
U-EC- 0011164526	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
U-EC- 0011164590	05/01/2022	Spontaneous	Non	European Economic	Not available	12-17 Years	Not Specified	Female	No	Lymph node pain (n/a - Unknown -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICS
										(n/a - Not Recovered/Not Resolved -),		- n/a - [n/a - n/a - n/a])	
										Vaginal haemorrhage (2d - Recovered/Resolved -)			
U-EC- 0011164711	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Hypoacusis (n/a - Recovered/Resolved -), Hypoaesthesia (n/a -			
										Recovered/Resolved -), Nausea (n/a -			
										Recovered/Resolved -), Pallor (n/a -			
										Recovered/Resolved			

										Recovered/Resolved - Other Medically			
EU-EC- 10011164805	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011164818	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011164884	05/01/2022	Spontaneous	Non Healthcare Professional	Area Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Unknown -), Hormone level abnormal (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										-), Intermenstrual bleeding (n/a - Unknown -)			
EU-EC- 10011164890	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Chua, G Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination 2021	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011164892	05/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunisation (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011164921	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown - Other Medically Important Condition) Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	05/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Chills (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011164950	03/01/2022	Spontaneous	Professional		NUL available	Years	Specified	remaie	INO	Chilis (1/a - Recovered/Resolved -), Dizziness (n/a - Unknown -), Dyspnoea (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10011164976	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Depressed level of consciousness (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Hypotension (n/a - Unknown -), Meningitis meningococcal (n/a - Fatal - Results in Death, Other Medically Important Condition), Purpura (n/a - Unknown -), Pyrexia (n/a - Fatal - Results in Death),			

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										Rash pruritic (n/a - Fatal - Results in Death), Septic shock (n/a -			
										Fatal - Results in Death, Other Medically Important Condition),			
										Vomiting (n/a - Fatal - Results in Death)			
EU-EC- 10011165318	05/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -), Swelling (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]),	ICSR
71.50	05/04/2022			N	Not a called	42.47	Not	lan-1-	N		COMPANY (TOTALAMEDAN)	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	
EU-EC- 100111165343	05/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination site pain (0d - Recovered/Resolved -)			
EU-EC- 100111165351	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011165382	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysphemia (10min - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Menstruation normal - n/a - [n/a - n/a - n/a])	ICSR
										Feeling cold (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition), Illness (n/a -			
										Unknown - Other Medically Important Condition), Tachycardia (n/a -			
										Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - Other			
EU-EC- 10011165384	05/01/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Malaise (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area						Caused/Prolonged Hospitalisation), Swelling (n/a -	Not applicable - [1d - n/a - Intramuscular])		
										Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a -			
										Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011165454	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovered/Resolved			
ا ps://dap . e	ma.euro	⊨ na.eu/ana	⊦ lvtics/saw	⊦ .dll?Go	I	1	I	I	I	I	I	I	55/67

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										- Other Medically Important Condition)			
EU-EC- 10011165469	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male		Blood glucose abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Immunisation (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011165865	05/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving -),			
										Feeling abnormal (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Nasopharyngitis (n/a - Recovering/Resolving			
										-), Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10011165913	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -),			
										Vaccination site pain (n/a - Recovered/Resolved -)			
EU-EC- 10011165926	05/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male		Amnesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN] [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011165927	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Hospitalisation), Sleep disorder (n/a - Unknown -)			
EU-EC- 10011166014	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011166034	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female		Arthralgia (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Oedema (n/a - Not Recovered/Not Resolved - Disabling),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10011166110	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Illness (n/a -			

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										Recovered/Resolved - Other Medically Important Condition), Menstrual disorder (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 100111166142	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Child	Male	No	Confusional state (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Hallucination (n/a - Not Recovered/Not Resolved - Disabling),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Disabling),			
										Sleep terror (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10011166517	05/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011166725	05/01/2022	Spontaneous		European Economic	Not available		Not Specified	Male	No	Recovering/Resolving -) Dizziness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
			Professional							- Disabling), Dust allergy (n/a - Not Recovered/Not Resolved -	n/a])		
										Disabling), Fatigue (2d - Recovered/Resolved - Disabling),			
										Malaise (2d - Recovered/Resolved - Disabling),			
										Mite allergy (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (2d - Recovered/Resolved - Disabling)			
EU-EC- 10011167047	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Child	Male	No	Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not			
	05/01/2022	Spontaneous			Not available		Adolescent	Male	No	Recovered/Not Resolved -) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
100111167226			Professional	Economic Area		Years				Unknown - Other	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC-	05/01/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011167362	-, -4, =062		Professional			Years				Unknown - Other Medically Important Condition), Vaccination failure	(S - n/a - n/a - [n/a - n/a - Intramuscular])		-5013
										(n/a - Unknown - Other Medically Important Condition)			

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EU-EC- 10011167370	05/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011167402	05/01/2022	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- 10011167445	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (20min - Recovered/Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Feeling hot (5min - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness (1min - Recovered/Resolved			
										- Life Threatening), Syncope (n/a - Recovered/Resolved			
EU-EC- 10011168677	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Life Threatening) 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- 10011168945	05/01/2022	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	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011169008	05/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011169363	05/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSF
EU-EC- 10011169366	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011169374	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Fatal - Results in Death), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Fatal - Results in Death), Headache (n/a - Fatal - Results in			
										Death), Musculoskeletal stiffness (n/a - Fatal			
										- Results in Death), Pyrexia (n/a - Fatal - Results in Death)			
EU-EC- 10011169376	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (36min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011169385	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011169392	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - 5mg - n/a])	ICSF
EU-EC- 10011169397	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSF
										Unknown -), Dyspnoea (n/a - Recovered/Resolved		[PERPHENAZINE] (C - n/a - n/a - [n/a - n/a - n/a]),	

										-), Dyspnoea (n/a - Unknown -),		[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C	
										Myalgia (n/a - Unknown -),		- n/a - n/a - [n/a - n/a - n/a]),	
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Oropharyngeal pain (n/a - Unknown -)			
EU-EC- 10011169400	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011169405	05/01/2022	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
				Economic Area						Chills (n/a - Unknown -),	Not applicable - [n/a - n/a - n/a])		
										Headache (n/a - Unknown -),			
										Heart rate increased (n/a - Unknown -),			
										Leukopenia (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Neutrophilia (n/a - Unknown -),			
										Palpitations (n/a - Unknown -),			
										Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown -)			
EU-EC- 10011169626	05/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	IC
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011169699	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011169701	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011169781	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Anxiety (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Blood test abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation),			

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											Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation), Tinnitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation), Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation), Weight decreased (n/a - Not Recovered/Not Resolved -			
											Caused/Prolonged Hospitalisation)			
	EU-EC- 10011170034	05/01/2022	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011170038	05/01/2022	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	ICSR
	511.50	05 (04 (2022					10.17				Vaccination failure (n/a - Unknown - Other Medically Important Condition)			1000
	EU-EC- 10011170322	05/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Female	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Syncope (1d - Unknown - Other Medically Important Condition),			
											Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10011170367	05/01/2022	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition),			
											Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important			

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										Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011170555	05/01/2022	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	ICSR
511.50	05/04/2022			-		12.17				Vaccination failure (n/a - Unknown - Other Medically Important Condition)			1000
EU-EC- 10011170822	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved -), Initial insomnia (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										- Unknown -), Rash pruritic (n/a - Not Recovered/Not Resolved -),			
EU-EC-	05/01/2022	Spontaneous		Non	Not available	12-17	Not	Male	No	Scratch (n/a - Unknown -) Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011170871			Professional	European Economic Area		Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Cardiac disorder (n/a	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										- Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a -			
										Unknown - Caused/Prolonged Hospitalisation),			
										Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Gastroenteritis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011170876	05/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011170893	05/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (n/a - Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-	Not reported	ICSR
										// Dizziness (n/a -	,, [20 1/0 1/0])		

								·	griopori			
									Recovering/Resolving -),			
									Fatigue (n/a - Recovering/Resolving			
									-),			
									decreased (n/a - Recovering/Resolving			
									Inappropriate schedule of product administration (n/a -			
									(n/a - Recovering/Resolving			
									Overdose (n/a -			
									Tunnel vision (n/a - Recovering/Resolving - Other Medically			
	Spontaneous			Not available	12-17	Not	Male	No	Important Condition) Headache (n/a -		Not reported	<u>ICSR</u>
5		Professional	European Economic Area		Years	Specified			-), Syncope (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
									- Other Medically Important Condition)			
	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a -		Not reported	ICSR
						,,			Cardiac failure (n/a - Unknown -),	applicable - [n/a3mL - Intramuscular])		
									Dizziness (n/a - Unknown -),			
									Electrocardiogram abnormal (n/a - Unknown -),			
									Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	<u>ICSR</u>
	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Multisystem		Not reported	<u>ICSR</u>
			Area						syndrome in children (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged	Not applicable - [1d6mL - Intramuscular])		
	Spontaneous		European	Not available	12-17 Vears	Adolescent	Male	No	Lung disorder (n/a -			ICSR
					rears				- Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving	Not applicable - [n/a - 1{DF} - Intramuscular])	12.5mg - n/a])	
05/01/2022	Spontaneous	Healthcare	Furonean	Not available	12-17	Adolescent	Male	No	Hospitalisation)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
		Professional		Not available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	
	Spontaneous	Professional	European	Not available	12-17 Years	Not Specified	Male	No	phosphokinase MB	[TOZINAMERAN] (S - COVID-	Not reported	<u>ICSR</u>
			Area						Unknown - Caused/Prolonged Hospitalisation),	applicable - [n/a - n/a - n/a])		
									Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
			I		1				Myocarditis (n/a -			
									Unknown - Life Threatening, Caused/Prolonged			
	05/01/2022 05/01/2022 05/01/2022 05/01/2022 05/01/2022 05/01/2022	05/01/2022 Spontaneous	05/01/2022 Spontaneous Healthcare Professional	D5/01/2022 Spontaneous Healthcare European Economic Area	DS/01/2022 Spontaneous Healthcare Professional European Not available	Beathcare Professional European Realthcare Realthcare Professional European Realthcare	05/01/2022 Spontaneous Healthcare Professional Economic Professional Professional Economic Professional Econ	Beathcare Non Professional European Not available 12-17 Not Specified Male	Disportaneous Healthcare Non Professional European Not available 12-17 Not Pears Specified No	Beginnering Residency September Residency Resi		No. Part P

EU-EC- 10011171441	05/01/2022	Spontaneous		European	Not available	12-17	Adolescent	Male	No	Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
:U-EC-	05/01/2022	Spontaneous	Healthcare Professional Non	Economic Area European	Not available	Years 12-17	Not	Female	No	-)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN]		ICS
10011171516			Healthcare Professional	Economic Area		Years	Specified			- Unknown -)	Not applicable - [n/a - 1{DF} - Intramuscular])	ETHINYLESTRADIOL] (C - Oral contraception - Dose not changed - [n/a - n/a - Oral])	
EU-EC- 10011171560	05/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011171589	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Psychomotor disadaptation syndrome (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICS
EU-EC- 10011171608	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICS
										Headache (1d - Recovered/Resolved -)			
EU-EC- 10011171656	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
10011171873		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011171999	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Loss of consciousness (0d - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (12h - Recovering/Resolving -), Syncope (0d -			
EU-EC- 10011172426	05/01/2022	Spontaneous	Healthcare Professional	Non	Not available		Not	Male	No	Recovering/Resolving -) Cellulitis (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
.0011172426			Professional	European Economic Area		Years	Specified			- Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Eye pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Eye swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Facial pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Herpes zoster (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Ocular hyperaemia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Scab (n/a - Recovered/Resolved			

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-11.50	05/04/2022					12.17				- Other Medically Important Condition)			1.00
EU-EC- L0011172431	05/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - Disabling, Other Medically Important Condition), Musculoskeletal discomfort (n/a - Not Recovered/Not Resolved - Disabling,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICS</u>
										Other Medically Important Condition), Weight bearing difficulty (n/a - Unknown - Disabling, Other Medically			
U-EC-	05/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Important Condition) Non-cardiac chest	COMIRNATY [TOZINAMERAN]	Not reported	ICS
.0011172437			Professional	European Economic Area		Years	Specified			pain (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	·	
:U-EC- 0011172478	05/01/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Child	Female	No	Loss of consciousness (1min	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Professional	Area						Recovered/Resolved - Disabling),	Not applicable - [n/a5mL - Intramuscular])		
										Seizure (n/a - Recovered/Resolved - Disabling)			
U-EC- 0011172697	05/01/2022	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
				Area						Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	n/a])		
										Dyspnoea (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Immunisation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Off label use (n/a - Unknown - Caused/Prolonged			
										Hospitalisation),			
EU-EC-	05/01/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Unknown -) Chills (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011172843	03/01/2022	Броншинова		Economic	Tot available	Years	Specified	remaie		Recovered/Not Resolved -), Headache (n/a - Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Tiot reported	100
										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 -), Nausea (n/a - Recovering/Resolving			
										-), Pyrexia (n/a - Not			
EU-EC-	05/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Recovered/Not Resolved -) Cardiac arrest (n/a -	COMIRNATY [TOZINAMERAN]	[PARACETAMOL] (C -	ICS
10011172923	03/01/2022	Spontaneous		European Economic Area	Not available	Years	Specified	riale	NO	Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PANACE INITIO] (C - n/a - n/a - n/a - n/a - fn/a - 200mg - Oral])	100
										Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important			
ns://dan.e										Condition),			64

										Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Head injury (n/a - Unknown -),			
										Hypotension (n/a - Unknown - Other Medically Important Condition),			
										Intestinal ischaemia (n/a - Fatal - Results in Death, Other Medically Important			
										Condition), Liver disorder (n/a - Unknown -),			
										Loss of consciousness (n/a - Unknown - Other Medically Important			
										Condition), Renal disorder (n/a -			
										Unknown -), Shock (n/a - Unknown - Other			
										Medically Important Condition),			
										Ventricular fibrillation (0d - Recovered/Resolved			
										- Other Medically Important Condition)			
EU-EC- 10011172993	05/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC-	05/01/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011173496			Professional	European Economic		Years	Specified			Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -		
				Area						Immunisation (n/a - Unknown -	n/a])		
										Caused/Prolonged Hospitalisation,			
										Other Medically Important Condition),			
										Myopericarditis (n/a -			
										Unknown - Caused/Prolonged Hospitalisation,			
										Other Medically Important			
										Condition), Night sweats (n/a -			
										Unknown -),			
										Off label use (n/a - Unknown -			
										Caused/Prolonged Hospitalisation,			
										Other Medically Important Condition)			
EU-EC- 10011173695		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myelitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011173890	05/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN]	ABILIFY 5 MG TABLETS	<u>ICSR</u>
10011173030			Professional			rears				-)	Not applicable - [1d - n/a - n/a])	[ARIPIPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder	
												- n/a - [n/a - n/a - n/a])	Ш
EU-EC- 10011174090	05/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011174493	05/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Disorientation (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
			, roressional	, ni ca						Condition), Feeling hot (n/a -	n/a])		
										Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Photopsia (n/a - Unknown - Other			

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										Medically Important Condition), Syncope (n/a -			
										Unknown - Other Medically Important Condition)			
EU-EC- 10011150349	04/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[INSULIN HUMAN REGULAR] (C - n/a - n/a - [n/a - 20{DF} - Subcutaneous])	ICSR
EU-EC- 100111150390	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dermatitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011150920	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011151103	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Recovering/Resolving -), Dyspnoea (n/a -			
										Recovering/Resolving -), Electrocardiogram			
										(n/a - Recovering/Resolving -),			
										Palpitations (n/a - Recovering/Resolving -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Troponin (n/a - Recovering/Resolving -)			
EU-EC- 10011151108	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gastrointestinal sounds abnormal (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Headache (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not			
										Recovered/Not Resolved -), Syncope (n/a - Not			
EU-EC-	04/01/2022	Spontaneous	Hoalthcare	Non	Not available	12-17	Not	Female	No	Recovered/Not Resolved - Other Medically Important Condition) Pain (n/a -	COMIDNATY (TOZINAMEDANI)	Not reported	ICCD
10011151166	04/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	Years	Specified	remale	INO	Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Parotid gland enlargement (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011151179	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011151185	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Areflexia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Guillain-Barre syndrome (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011151195	04/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]),	Not reported	ICSF
											[SODIUM VALPROATE, VALPROIC ACID] (S - Epilepsy - Unknown - [n/a - n/a - n/a])		
EU-EC- 10011151197	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	[CLOBAZAM] (C - n/a - n/a - [n/a - 40mg - n/a])	ICSR

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										Condition), Fatigue (n/a - Unknown -),			
										Generalised tonic- clonic seizure (n/a - Unknown - Other Medically Important Condition), Malaise (n/a -			
EU-EC- 10011151233	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011151243	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011151855	04/01/2022	Spontaneous	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011151881	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Iridocyclitis (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR



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