Line Listing Report

Time run: 30/11/2022 11:22:32 Primary Suspect/interacting Concomitant/Not ΕV Source Patient Drug List (Drug Char Administered Drug List Primary Patient Parent Reaction List PT (Drug Char - Indication EU Local Gateway Country Literature Age Group Patient Indication PT ICSR Report Type Source Child (Duration - Outcome Age Number Receipt for Reference (as per Sex Action taken PT - Action taken -Form Oualification Group Report Seriousness Criteria) [Duration - Dose -Regulatory [Duration - Dose reporter) Purposes Route]) Route]) EU-EC-25/09/2021 Spontaneous Healthcare Not 12-17 Adolescent Female Myocarditis (9d -COMIRNATY Not reported <u>ICSR</u> European No [TOZINAMERAN] (S 10010132454 Professional Economic available Years Recovered/Resolved -COVID-19 Area Important Condition) immunisation - Not applicable - [n/a -Intramuscular]) FU-FC-25/09/2021 Spontaneous Non European Not 12-17 Not Female No Headache (13d -COMTRNATY Not reported **ICSR** 10010132477 Economic [TOZINAMERAN] (S Healthcare available Specified Years Recovered/Resolved -Professional Area COVID-19 immunisation - Not applicable - [n/a -Menstruation delayed (13d -1{DF} - n/a]) Recovered/Resolved Heart rate increased EU-EC-25/09/2021 Spontaneous Non 12-17 COMIRNATY **ICSR** European Not Not Female Not reported 10010132485 [TOZINAMERAN] (S Healthcare Economic available Years Specified (n/a - Not Area Recovered/Not Professional COVID-19 immunisation - Not applicable - [n/a -Resolved -), 1{DF} - n/a]) Hyperhidrosis (n/a -Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -). Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -). Tremor (n/a - Not Recovered/Not Resolved -), Visual impairment (n/a - Not Recovered/Not Resolved -) COMIRNATY [TOZINAMERAN] (S EU-EC-25/09/2021 Spontaneous Non 12-17 Female <u>ICSR</u> European Arthralgia (n/a - Not Not reported 10010132696 Healthcare Economic available Years Specified Recovered/Not Resolved -), COVID-19 Professional Area immunisation - Not applicable - [n/a -Nausea (n/a - Not 1{DF} - n/a]) Resolved - 1 Polymenorrhoea (7d -Recovered/Resolved -FU-FC-25/09/2021 Spontaneous Non European Not 12-17 Not Female No COMIRNATY Not reported **ICSR** 10010132889 Healthcare Specified [TOZINAMERAN] (S Economic available Years Professional COVID-19 immunisation - Not applicable - [n/a 1{DF} - n/a]) FU-FC-25/09/2021 Spontaneous Non European Not 12-17 Not Female No Injection site pain (7d COMIRNATY Not reported ICSR 10010132998 Healthcare Specified [TOZINAMERAN] (S available Economic Years Recovered/Resolved COVID-19 Area immunisation - Not applicable - [n/a -Lymphadenopathy 1{DF} - n/a]) Recovered/Resolved 25/09/2021 Spontaneous Non 12-17 Not Female No Headache (12h -COMIRNATY Not reported <u>ICSR</u> European 10010133002 Healthcare Economic available Years Specified Recovered/Resolved -[TOZINAMERAN] (S COVID-19 Professional Area immunisation - Not applicable - [n/a -Malaise (n/a - Not 1{DF} - n/a]) Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -) Not Fatigue (1d -FU-FC 25/09/2021 Spontaneous Non Not 12-17 Male COMTRNATY [PARACETAMOL] (C -<u>ICSR</u> No [TOZINAMERAN] (S 10010133215 Healthcare Economic available Years Specified Recovered/Resolved n/a - n/a - [n/a - n/a -

Professional

Area

COVID-19

1{DF} - n/a])

Headache (1d -

Recovered/Resolved -

immunisation - Not

applicable - [n/a -

n/a])

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										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (2d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10010133243	25/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010133326	25/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED O.A.C. [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Headache (0d - Recovered/Resolved -			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (1d - Recovered/Resolved -)			
EU-EC- 10010133398	25/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010133399	25/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010133501	25/09/2021	Spontaneous		Economic	Not available		Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Listless (2d - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10010116514	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010116517	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (42d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - n/a - n/a - [n/a - 1{DF} - n/a])	ICSR
										Hyperhidrosis (42d - Not Recovered/Not Resolved -),			
										Pain in extremity (42d - Not Recovered/Not Resolved -)			
EU-EC- 10010116520		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Paresis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010118471			Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Herpes zoster (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010118610	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovering/Resolving -), Vaccination site lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										(n/a - Recovering/Resolving -)	Intramuscular])		

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EU-EC- 10010118701	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved -), Hyperventilation (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010118723	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
										reaction (n/a - Not Recovered/Not Resolved -)	Incamascalary)		
EU-EC- 10010118837	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
:U-EC- .0010118867	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
U-EC- 10010119001	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[OXCARBAZEPINE] (C - Mental disorder - n/a - [n/a - 900mg - Oral])	ICS
EU-EC- 10010119874	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CIRCADIN [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - n/a]), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Headache - n/a - [n/a - n/a - n/a]),	
										Lymph node pain (n/a - Unknown - Other Medically Important Condition),		[PARACETAMOL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a])	
										Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Nausea (n/a -			
										Recovering/Resolving - Other Medically Important Condition), Vaccination site mass			
										(4d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (3d - Recovered/Resolved - Other Medically			
EU-EC- 10010119879	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Arthralgia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										- Life Threatening, Caused/Prolonged Hospitalisation), Inflammation (n/a - Not Recovered/Not			
										Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Joint stiffness (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged			

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										Hospitalisation),			
										Musculoskeletal stiffness (10d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain			
										Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Rash (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010120026	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunication - Not applicable - [1d -	[ETONOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR
										Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-	24/00/2021	Casakanania	Non	Filmanaan	Not	12.17	Net	Mele	No	Muscle spasms (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIDNATY	Networked	TCCD
10010120552	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a - n/a])		
										Pneumonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010120797	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (10min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010121344	24/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Unknown - Life Threatening),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Blood pressure increased (n/a - Unknown -),	n/a - n/a])		
										Chest pain (n/a - Unknown -),			
										Dyspnoea (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Heart rate increased (n/a - Unknown -),			
										Palpitations (n/a - Unknown -),			
										Presyncope (n/a - Unknown -)			
EU-EC- 10010121350	24/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (0d - Recovered/Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [n/a - n/a - n/a])		
EU-EC- 10010122058	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary mass (n/a - Not Recovered/Not Resolved -), Axillary pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010122104	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC- 10010122176	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Unknown -), Somnolence (0d - Recovered/Resolved -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010122477	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010122646	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Palpitations (5s - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010122956	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010123199		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),		NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010123486	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pain (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010123533	24/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available		Not Specified	Female	No	Condition) Dizziness (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

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				Area), Dyspnoea (1d - Recovered/Resolved -	- Immunisation - n/a - [n/a - n/a - n/a])		
), Rash macular (1d - Recovered/Resolved -			
EU-EC- 10010123591	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010124013	24/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC-	24/00/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMEDAN	Not reported	ICCI
10010124064	24/09/2021	Sportaneous	Healthcare	Non European Economic Area	available	Years	Specified	male	NO	Drug hypersensitivity (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	Not reported	ICSF
										Eye swelling (n/a - Unknown - Other Medically Important Condition),	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (S - Tooth extraction -		
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Unknown - [n/a - n/a - n/a])		
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010124249	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010124722	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Papule (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSF
										Rash (n/a - Not Recovered/Not Resolved -),	Intramuscular])		
EIL EC	24/00/2021	Coordon	Non	N	NI-A	12.17	Niet	N4-1-	NI-	Rash pruritic (n/a - Not Recovered/Not Resolved -)	TOTINAMEDAN	Not you also d	Tech
EU-EC- 10010125051	24/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSF</u>
										Recovered/Not Resolved -), Feeling abnormal (n/a	n/a - Intramuscular])		
										- Unknown -), Headache (n/a - Not			
										Recovered/Not Resolved -), Heart rate increased			
										(n/a - Not Recovered/Not			
										Resolved -), Illness (n/a -			

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EU-EC- 10010125058		Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Unknown -), Palpitations (n/a - Unknown -), Somnolence (n/a - Unknown -), Vomiting (n/a - Unknown -), Cold sweat (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Patigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Heart rate increased (n/a - Not Recovered/Not Resolved -), Heypersomnia (n/a - Unknown -), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersomnia (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Unknown -), Vomiting (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010125258	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug -	Not reported	ICSR
EU-EC- 10010125268	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling hot (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10010125396	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	-) Diarrhoea (n/a - Unknown -), Rectal haemorrhage (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010125398	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010125413	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (n/a - Recovering/Resolving -), Fatigue (0d -	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										Recovered/Resolved -), Nausea (n/a - Recovering/Resolving			
EU-EC- 10010125428	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10010125498	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125540	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125548	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Joint swelling (3d - Not Recovered/Not Resolved -), Peripheral swelling (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125595	24/09/2021	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 - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125615	24/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved -), Influenza like illness (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICS
EU-EC- 10010125722	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
10010125783		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125809	24/09/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010125862	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN] (S [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Illness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition), Pain of skin (n/a - Not Recovered/Not			
										Resolved - Other Medically Important Condition), Somnolence (n/a -			
										Recovered/Resolved - Other Medically Important Condition),			8.

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										Wheezing (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010126140	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [1d - 1{DF} -	Not reported	ICSR
										Dry mouth (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Encephalitis (18d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Facial paralysis (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Gait disturbance (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010126312	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myopericarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [32d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010126322	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Thrombophlebitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		Not reported	ICSR
EU-EC- 10010126384	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving -),	applicable - [n/a - n/a - n/a])		
										Menstrual disorder (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -), Pyrexia (n/a -			
										Recovering/Resolving -)			
EU-EC- 10010126500	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (23d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010126502	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Feeling hot (2d - Recovering/Resolving -),			
										Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (2d -			
										Recovering/Resolving -)			
EU-EC- 10010126505	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (31d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010126507	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (30d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010126509	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (3d - Recovered/Resolved -)			
EU-EC- 10010126510	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (9d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

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										Nausea (9d - Recovered/Resolved -),	- Immunisation - n/a - [n/a - n/a - n/a])		
										Vomiting (1d - Recovering/Resolving			
EU-EC- 10010126511	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paranasal sinus discomfort (7d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126512	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010126513	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericardial effusion (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Seizure (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010126514	24/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Movement disorder (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126515	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Menstrual disorder (5d - Recovered/Resolved -),			
										Pyrexia (5d - Recovering/Resolving -)			
EU-EC- 10010126520	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126521	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (n/a - Recovered/Resolved -),			
										Peripheral coldness (n/a - Recovered/Resolved -)			
EU-EC- 10010126529	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126534	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling of eyelid (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126536	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126537	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anosmia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126541	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126542	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010126543		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (64d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126545		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Chest pain (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126547	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>

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										Vomiting (0d - Recovered/Resolved -			
EU-EC- 10010126548	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126549	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126550	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Movement disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscle twitching (n/a			
EU EC	24/00/2021	Casabanasus	Non	Formanan	Nati	12.17	Adalasasak	Famala	Na	- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMPONIATY	Not verented	ICCD
EU-EC- 10010126552		·	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Appendicitis (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126554	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010126555	24/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (86d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010127054	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye swelling (n/a - Recovered/Resolved -), Hypersensitivity (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE	[LORATADINE] (C - n/a - Dose not changed -)	ICSR
										Recovered/Resolved -), Pharyngeal paraesthesia (n/a -	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not		
EU-EC-	24/09/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Dyspnoea (n/a -	applicable - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10010127108	_ ,, 05, 2022	Spontanisous	Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -		<u> </u>
										Unknown -), Swelling face (n/a - Recovered/Resolved - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010127668	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (20d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DESOGESTREL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ISOTRETINOIN] (C - n/a - Unknown - [n/a -	ICSR
EU-EC- 10010127747	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19	n/a - n/a]) Not reported	ICSR
										Heart rate irregular (n/a - Not Recovered/Not Resolved - Disabling),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Menstruation irregular (n/a - Not Recovered/Not Resolved - Disabling),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10010127773	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Resolved -), Loss of consciousness (n/a -	n/a - n/a])		
										Recovered/Resolved -), Movement disorder			
										(n/a - Not Recovered/Not			

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										Resolved -), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Myalqia (n/a - Not			
										Recovered/Not Resolved -), Neck pain (n/a - Not			
										Recovered/Not Resolved -), Pyrexia (n/a -			
EU-EC-	24/09/2021	Spontaneous		European	Not	12-17	Not	Male	No	Recovered/Resolved -) Alpha globulin	COMIRNATY	Not reported	<u>ICSR</u>
10010128294			Healthcare Professional	Economic Area	available	Years	Specified			increased (n/a - Unknown -), C-reactive protein increased (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
										Unknown -), Discomfort (n/a - Recovered/Resolved -	Intramuscular])		
), Fatigue (n/a - Recovered/Resolved -			
										Mean cell haemoglobin			
										decreased (n/a - Unknown -), Pyrexia (n/a - Unknown -)			
EU-EC- 10010128738	24/09/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Area						Dysstasia (n/a - Unknown -), Fatigue (n/a -	applicable - [n/a - n/a - n/a])		
										Unknown -), Heart rate decreased (n/a - Unknown - Other Medically Important Condition),			
										Hypotension (n/a - Unknown -),			
										Nausea (n/a - Unknown -),			
										Peripheral coldness (n/a - Unknown -), Vomiting (n/a -			
	2 4 /22 /222									Unknown -)			
EU-EC- 10010129051		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010129067	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	ZEBINIX [ESLICARBAZEPINE ACETATE] (C - Epilepsy - n/a - [n/a - 600mg - n/a]), ZEBINIX	<u>ICSR</u>
												[ESLICARBAZEPINE ACETATE] (C - Epilepsy - n/a - [n/a - 800mg - n/a])	
EU-EC- 10010129088	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	1{DF} - n/a])		
EU-EC- 10010129157	24/09/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (15h - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Dizziness (15h - Recovered/Resolved -),	immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])		
										Fall (15h - Recovered/Resolved -),			
										Feeling cold (15h - Recovered/Resolved -			

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), Head injury (15h - Recovered/Resolved -),			
										Loss of consciousness (15h - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (15h - Recovered/Resolved -			
EU-EC- 10010129356	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown - More in ICSR])	Not reported	ICSR
										Condition), Weight decreased (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010129414	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
EU-EC- 10010129559	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ocular myasthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - immunisation - I{DF} -	Not reported	ICSR
EU-EC- 10010129605	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (1d - Recovered/Resolved - Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010129607	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	24/00/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Eamala	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition) Fall (n/a - Unknown -	COMIRNATY	Not reported	ICSR
10010129907	24/09/2021	Sportaneous		Economic	available	Years	Adolescent	Гепае	NO	Loss of consciousness (n/a - Unknown -),	[TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	<u>ICSK</u>
EU-EC- 10010130160	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Unknown -) Aphonia (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a -	n/a - n/a])		
										Recovered/Resolved - Other Medically Important Condition), Neck pain (n/a - Recovered/Resolved -			
										Other Medically Important Condition), Peripheral swelling (n/a -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010130314	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010130918	24/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	

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										Headache (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[TRETINOIN] (C - n/a - n/a - [n/a - n/a - n/a])	
										Injection site pain (1d - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10010101170	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010101230	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Back pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
										Recovering/Resolving -), Dysuria (n/a -	Intramuscular])		
										Recovering/Resolving -),			
										Kidney infection (n/a - Recovering/Resolving -)			
EU-EC- 10010103523	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010103795	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010104057	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Recovered/Resolved With Sequelae -), Diarrhoea (n/a -	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved With Sequelae -), Haematochezia (n/a - Recovered/Resolved			
										With Sequelae - Other Medically Important Condition),			
EU-EC-	22/00/2021	Coontonoous	Llogithean	European	Not	12.17	Not	Mala	No	Pyrexia (n/a - Recovered/Resolved With Sequelae -)	COMTONIATY	NOT AVAILABLE (C. p./p.	ICCD
10010104632	23/09/2021	Spontaneous		Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [n/a - 125mg - n/a])	ICSK
EU-EC- 10010105071	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Disabling),	applicable - [n/a - n/a - Intramuscular])		
										Fatigue (n/a - Recovered/Resolved - Disabling),			
										Headache (n/a - Recovered/Resolved - Disabling),			
										Pyrexia (n/a - Recovered/Resolved - Disabling),			
										Suffocation feeling (n/a - Recovered/Resolved - Disabling)			
EU-EC- 10010105160	23/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

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										Chest pain (n/a - Unknown - Other Medically Important Condition),	n/a - Intramuscular])		
										Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010105821	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010105870	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Administration site pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved -)	1{DF} - n/a])		
EU-EC- 10010106256	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (9d - Recovered/Resolved -), Eye pain (4d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved			
										-), Myalgia (9d - Recovered/Resolved -			
										Tremor (8d - Recovered/Resolved -			
EU-EC- 10010106257	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (6wk - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Hyperhidrosis (6wk - Recovered/Resolved -), Pain in extremity	Intramuscular])		
										(6wk - Recovered/Resolved -			
EU-EC- 10010106262	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (0d - Not Recovered/Not Resolved -), Injection site pain (1d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- Not Recovered/Not Resolved -), Nausea (1d - Not Recovered/Not			
EU-EC- 10010106264	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Dizziness (12d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
			Troressional	Arca						Fatigue (12d - Not Recovered/Not Resolved -),	- [n/a - n/a - Intravenous (not otherwise specified)])		
										Headache (12d - Not Recovered/Not Resolved -),			
										Somnolence (12d - Not Recovered/Not Resolved -)			
EU-EC- 10010106267	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (1d - Recovered/Resolved -), Fatique (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Myalgia (1d -			
	23/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Oral herpes (n/a -	COMIRNATY	Not reported	ICSR
10010106506			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation - n/a		

EU-EC-		Spontaneous		European	Not		Adolescent		No	Fatigue (1d -	COMIRNATY	Not reported	ICSR
10010106643			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Headache (0d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Resolved -),			
EU-EC-	23/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Injection site pain (6d - Recovered/Resolved -) Fatigue (2d -	COMIRNATY	Not reported	ICSR
10010106648	23/03/2021	Spontaneous	Healthcare	Economic Area	available	Years	Adolescent	remale	INO	Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>1C3K</u>
										Headache (0d - Recovering/Resolving -),			
										Influenza (2d - Recovering/Resolving -),			
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10010106686	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (0d - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010106703	23/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Injection site pain (2d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional	Area						Resolved - Caused/Prolonged Hospitalisation),	- Immunisation - n/a - [n/a - n/a - n/a])		
										Lymphadenopathy (2d - Not Recovered/Not			
										Resolved - Caused/Prolonged Hospitalisation),			
										Seizure (0d - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010107063	23/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010107168	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast pain (30min - Recovered/Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
										Chills (1d - Recovered/Resolved -),	n/a - n/a])		
										Fatigue (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -			
EU-EC- 10010107174	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Condition), Anosmia (n/a - Not Recovered/Not Resolved -),	[n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hot flush (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not			
										Resolved -), Vaccination site swelling (n/a - Not Recovered/Not			
EU-EC-	23/09/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Resolved -) Vertigo (n/a -	COMIRNATY	Not reported	ICSR
10010107178			Professional	Economic Area	available	Years				Unknown -)	[TOZINAMERAN] (S		

											- n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10010107214	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
EU-EC- 10010107228	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010107247	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010107254	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSF
EU-EC- 10010107306	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107324	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lip oedema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107359	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010107367	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107409	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Tonsillitis streptococcal (11d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSR
EU-EC- 10010107442	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010107459	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hordeolum (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107481	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breast inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107496	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010107526	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphthous ulcer (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010107558	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010107577	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010107584	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10010107593	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Vaccination site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	23/09/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Recovering/Resolving -) Loss of consciousness	Intramuscular]) COMIRNATY	Not reported	ICSR
10010107938	23,03,2021	Spontaneous	Professional	European Economic Area	available	Years	Specified	Citale		(n/a - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSIK
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010107950	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asterixis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Depressed level of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
5U 50	22/00/2024					12.17			N	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMPANY		TOCO
EU-EC- 10010107959	23/09/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Choking sensation (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
										Sensory disturbance (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010107980	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010108113	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[DIAZEPAM] (C - Tension headache - n/a - [116d - 2mg - Oral]),	ICSR
				Area						Confusional state (n/a - Not Recovered/Not Resolved - Disabling),	immunisation - Not applicable - [1d - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	
										Conversion disorder (n/a - Not Recovered/Not Resolved - Disabling),		[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]),	
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		[FLUTICASONE PROPIONATE] (C - Seasonal allergy - n/a - [n/a - n/a - Nasal]),	
										Tremor (n/a - Not Recovered/Not Resolved -)		[NORTRIPTYLINE, NORTRIPTYLINE HYDROCHLORIDE] (C - Prophylaxis - n/a - [n/a - 25mg - Oral])	
EU-EC- 10010108226	23/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Fatigue (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>

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				Area), Headache (0d - Recovered/Resolved -),	- COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Insomnia (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10010108233	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Nasal congestion (n/a - Unknown -),	immunisation - Not applicable - [1d - n/a - n/a])		
										Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a -			
										Unknown -), Vaccination site pain			
EU-EC- 10010108448	23/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	(n/a - Unknown -) Cerebral artery occlusion (n/a - Not	COMIRNATY [TOZINAMERAN] (S	[BUDESONIDE] (C - n/a - n/a - [n/a - n/a -	ICSR
				Area						Recovered/Not Resolved - Caused/Prolonged	- n/a - n/a - [1d - n/a - Intramuscular])	Respiratory (inhalation)]),	
										Hospitalisation), Cerebral infarction		[LEVOTHYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a - Oral])	
										(n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Thrombectomy (n/a -			
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Thrombolysis (n/a - Not Recovered/Not Resolved -			
EU-EC-	23/09/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Caused/Prolonged Hospitalisation) Chills (n/a - Not	COMIRNATY	Not reported	ICSR
10010108502		·	Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	·	
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site erythema (n/a - Not Recovered/Not Resolved -),			
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (n/a - Not Recovered/Not			
										Resolved -), Malaise (n/a - Not Recovered/Not			
										Resolved -), Nausea (n/a - Not Recovered/Not			
										Resolved -), Rash (n/a - Not Recovered/Not			
EU-EC- 10010108768	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010108785	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Myocarditis (1d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC-	23/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Not	No	Myocarditis (n/a -	Subcutaneous]) COMIRNATY	Not reported	ICSR
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10010108796			Healthcare Professional	Economic Area	available	Years		Specified		Unknown - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])		
EU-EC- 10010108825	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		Not reported	ICSR
EU-EC- 10010109259	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved -),			
										Lymphadenopathy (n/a - Recovered/Resolved -)			
EU-EC- 10010109323	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10010109362	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Irritable bowel syndrome (n/a - Not Recovered/Not Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved -)	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010109481	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010109690	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Asthenia (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (n/a - Recovered/Resolved -),			
										Malaise (n/a - Recovered/Resolved -),			
										Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a -			
										Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -			
EU-EC- 10010110028	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010110100	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Myopericarditis (n/a - Not Recovered/Not Resolved -			

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										Caused/Prolonged Hospitalisation)			
EU-EC- 10010110510	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010110569	23/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown - Other Medically Important Condition), Contusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SODIUM CHLORIDE] (C - Postural orthostatic tachycardia syndrome - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010110653	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CYCLIZINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thirst (n/a - Unknown			
EU-EC- 10010110900	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC-	23/09/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) Psoriasis (n/a - Not	n/a - n/a]) COMIRNATY	Not reported	ICSR
10010111350	23/03/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Specified	Haic		Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICON
EU-EC- 10010111391	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010111452	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010111716	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10010111748	23/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved -			
EU-EC- 10010111758	23/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Haemorrhage subcutaneous (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Unknown -), Subcutaneous			
										haematoma (n/a - Unknown -)			
EU-EC- 10010111901	23/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>

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			Professional	Area), Headache (n/a - Recovered/Resolved -),	- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Intermenstrual bleeding (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -			
EU-EC- 100101111924	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 100101111927	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 100101111936	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 100101111945	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 100101111948	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Lip oedema (2d - Recovered/Resolved -), Urticaria (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112006	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112009	23/09/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112039	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (1d - Recovered/Resolved -), Pruritus (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112059	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (3d - Recovered/Resolved -), Faeces soft (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010112060	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010112084		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Alopecia areata (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Subcutaneous])	Not reported	ICSR
EU-EC- 10010112085	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010112108		Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (2d - Recovered/Resolved -	COMIRNATY	Not reported	ICSR

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				Area), Asthenia (2d - Recovered/Resolved -), Decreased appetite (2d - Recovered/Resolved -	- COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])		
), Headache (2d - Recovered/Resolved -),			
										Vomiting (2d - Recovered/Resolved -			
EU-EC- 10010112280	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010112325	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Encephalitis (37d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Multisystem inflammatory syndrome in children (37d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Sinus arrhythmia (37d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010112329	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Conjunctivitis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Joint swelling (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1,,4])		
										Multisystem inflammatory syndrome in children (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010112390	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010112559	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menarche (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010112613	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Polymenorrhoea (n/a -		Not reported	ICSR
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EU-EC- 10010112714	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (6d - Recovered/Resolved -), Cough (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

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EU-EC- 10010112914	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010112925	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112944	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010112988	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010113135	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Necovered/Resolved - Necovered/Resolved - Necovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Necovered/Resolved - Necovered/Resolv	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010113419	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dysaesthesia (n/a - Unknown - Other Medically Important Condition), Paraparesis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010113780	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pancreatitis acute (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010114235	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved - Disabling), Back pain (n/a - Not Recovered/Not Resolved - Disabling), Groin pain (n/a - Not Recovered/Not Resolved - Disabling), Mobility decreased (n/a - Not Recovered/Not Resolved - Disabling), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Disabling), Neck pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (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- 10010114246	23/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Diarrhoea (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - n/a - n/a])		
EU-EC- 10010114308	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Syncope (0d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010114379	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010114512	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Diplegia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nystagmus (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vaccination error (n/a - Unknown -)			
EU-EC- 10010115517	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010115521	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	AVAMYS 27.5 MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a	
												- n/a - [n/a - n/a - n/a]), [CICLESONIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010115615	23/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Amnesia (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Contusion (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown -			
										Other Medically Important Condition), Heart rate decreased			

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										(n/a - Unknown - Other Medically Important Condition),			
										Mydriasis (n/a - Unknown - Other Medically Important Condition),			
										Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010115676	23/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Delusion (n/a - Recovering/Resolving -), Hallucinations, mixed (n/a - Recovering/Resolving - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010115786	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Hypersomnia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Resolved - Disabling), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling), Pain (n/a - Not Recovered/Not			
EU-EC- 10010115820	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - Disabling) Heavy menstrual bleeding (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 10010115917	23/09/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Unknown -) Rash (n/a - Recovered/Resolved -	applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC-	22/00/2021	Spontaneous	Professional		Not	12-17	Not	Male	No) Chills (n/a -	- n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
10010116138			Healthcare Professional	Economic	available	Years	Specified			Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010116980	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010116983	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010117004	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No) Osteoarthritis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC- 10010117026	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Mastitis (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010117030	23/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (30d - Recovered/Resolved -), Headache (30d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Palpitations (8d - Recovered/Resolved -), Testicular swelling (25d - Recovered/Resolved -),			
										Vomiting (30d - Recovered/Resolved -			
EU-EC- 10010117044	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Recovering/Resolving -), Rash erythematous (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010117096	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown - More in ICSR])	Not reported	ICSR
EU-EC- 10010117395	23/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Anxiety (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										-), Blood pressure decreased (n/a - Recovering/Resolving -),			
										Chills (n/a - Recovering/Resolving -),			
										Cold sweat (n/a - Recovering/Resolving -),			
										Feeling abnormal (n/a - Recovering/Resolving			
										-), Feeling cold (n/a - Recovering/Resolving			
										Grip strength decreased (n/a -			
										Unknown -), Hypoaesthesia (n/a - Recovering/Resolving			
										Muscular weakness (n/a - Recovering/Resolving -),			
										Peripheral coldness (n/a - Unknown -),			
										Peripheral vascular disorder (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Visual impairment (n/a - Recovering/Resolving			
EU-EC- 10010117527	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Electroencephalogram abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

				1			1			Condition),			
										Encephalitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Encephalopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010117662	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatique (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved -), Malaise (n/a - Not	1{DF} - n/a])		
										Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not			
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010117839	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
											COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10010117842	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010117851	23/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Migraine (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Paraesthesia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
10010117880		·	Non Healthcare Professional		Not available	12-17 Years	Child	Male	No	Malaise (5d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010117954	23/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (0d - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

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										Important Condition), Presyncope (0d -			
										Recovered/Resolved - Other Medically			
										Important Condition)			\perp
EU-EC- 10010118094	23/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICS</u> F
										Vomiting (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010088364	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICS
										Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition),	[n/a - 1{DF} - Intramuscular])		
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010088367	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICS
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	[n/a3mL - Intramuscular])		
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Hyperventilation (n/a			
										Recovering/Resolving Other Medically Important Condition),			
										Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pharyngeal erythema (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Sopor (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tonsillar erythema (n/a - Recovering/Resolving			
										- Other Medically Important Condition)			
EU-EC-	22/09/2021	Spontaneous		European	Not	12-17	Not	Female	No	Vertigo (n/a -	COMIRNATY	Not reported	ICSF
10010089735			Professional	Economic Area	available	Years	Specified			Unknown -), Vision blurred (n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Onknown)	.3mL -		
EU-EC- 10010089736	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vision blurred (n/a - Unknown -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
											applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10010089740	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -), Hypoaesthesia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Recovering/Resolving	.3mL - Intramuscular])		
EU-EC- 10010089742	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Vertigo (n/a - Unknown -)	immunisation - Not applicable - [n/a -		

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											.3mL - Intramuscular])		
EU-EC- 10010089744	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Nausea (n/a - Unknown -), Vomiting (n/a -	immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
										Unknown -)	intramuscular j)		
EU-EC- 10010089746	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010089749	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -), Vision blurred (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010089751	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010089994	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSF
EU-EC- 10010090291	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved -), Hyperhidrosis (n/a - Unknown -), Pallor (n/a - Unknown -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010090800	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [85d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010090812	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Lethargy (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010091880	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiovascular disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC-	22/09/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Dizziness (2wk - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
10010092071			Professional	Area)	immunisation - Not applicable - [n/a - .3mL -		
10010092071 EU-EC-	22/09/2021	Spontaneous		Area European	Not	12-17	Not	Female	No	Diarrhoea (1d -	immunisation - Not applicable - [n/a -	Not reported	ICSF

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										Fatigue (1d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Headache (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -),			
										Vomiting (1d - Recovered/Resolved -)			
10010092762		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010093286	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
				71100						Lethargy (n/a - Not Recovered/Not Resolved -),	applicable - [1d - n/a - n/a])		
										Pain (n/a - Not Recovered/Not Resolved -),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pleurisy (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010093432	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Headache (2d - Recovering/Resolving -),	applicable - [n/a - .3mL - Intramuscular])		
										Myalgia (2wk - Recovering/Resolving -)			
EU-EC- 10010093552	22/09/2021	Spontaneous			Not available	12-17 Years	Adolescent	маје	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010093788	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010093821	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			

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										Condition), Rhabdomyolysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010094177	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Paraesthesia (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	22/00/2021	Spontaneous	Non	Non	Not	12-17	Not	Fomala	No	Sinus bradycardia (n/a - Unknown - Other Medically Important Condition)	TOZINAMEDANI	Not reported	ICCD
10010094226	22/09/2021	Sportaneous	Healthcare	Non European Economic Area	Not available	Years	Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC-	22/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition) Electrocardiogram	n/a - n/a]) TOZINAMERAN	[DESOGESTREL] (C -	ICSR
10010094324			Healthcare	European Economic Area	available	Years	Specified			abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a - n/a - [n/a - n/a - n/a])	
										Heart rate (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010094342	22/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (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
										Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	1ya - 1yaj)		
										Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fall (n/a - Recovered/Resolved -), Feeling abnormal (n/a			
EU-EC-	22/09/2021	Spontaneous		European	Not	12-17	Not	Female	No	- Recovered/Resolved -) Intermenstrual	COMIRNATY	KEPPRA 100 MG/ML	ICSR
10010094812			Healthcare Professional		available	Years	Specified			bleeding (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ORAL SOLUTION [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010094854	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (4d - Recovered/Resolved -), Varicella (4d -	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR	Not reported	ICSR
										Recovered/Resolved -	DISPERSION FOR INJECTION [TOZINAMERAN] (S		

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											immunisation - n/a - [n/a3mL -		
EU-EC- 10010094940	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Recovered/Resolved -), Influenza like illness (48h -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a - More in ICSR])	Not reported	ICSF
										Recovered/Resolved -), Pain (48h - Recovered/Resolved -			
										Pyrexia (48h - Recovered/Resolved -			
EU-EC- 10010095334	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Chest discomfort (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
	22/02/2021			_		10.17				Myocarditis (n/a - Unknown - Other Medically Important Condition)			100
EU-EC- 10010095490	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSF</u>
EU-EC- 10010095495	22/09/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
			rioressional	Area						Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Hospitalisation), Electrocardiogram change (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010096046	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010096077	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S	Not reported	ICSF
										Recovered/Not Resolved -), Headache (n/a - Not	- COVID-19 - n/a - [n/a - n/a - n/a])		
										Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not			
										Resolved -), Nausea (n/a - Not Recovered/Not			
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010096098	22/09/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - Life Threatening,	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF

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				Economic Area						Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Life	immunisation - Not applicable - [n/a - n/a - n/a])		
										Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Life Threatening,			
										Caused/Prolonged Hospitalisation)			
EU-EC- 10010096144	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010096150	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown -), Headache (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DESOGESTREL, DESOGESTREL EP] (C - Dysmenorrhoea, Menometrorrhagia - n/a - [n/a - 75ug - Oral]),	ICS
), Heavy menstrual bleeding (n/a - Unknown -),		[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 120mg - n/a])	
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010096153	22/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										-), Nausea (n/a -			
EU-EC-	22/09/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Unknown -) Intermenstrual	COMIRNATY	Not reported	ICS
10010096270	, ,		Healthcare Professional	Economic	available	Years	Specified			bleeding (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010096595	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ascites (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICS
										Recovering/Resolving	inclumusedially		
EU-EC- 10010096597	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICS
										Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010097009	22/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (n/a - Unknown -), Influenza like illness	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC-	22/00/2024	Spontaneous	Healthcara	European	Not	12-17	Adolescent	Famala	No	(n/a - Unknown -) Dysmenorrhoea (n/a -	1{DF} - Intramuscular]) COMIRNATY	Not reported	ICS
10010097099	<u> </u>	эропсанесиѕ	Professional	Economic Area	available	Years	AUDIESCEIT	Terriale	INU	Not Recovered/Not Resolved -), Heavy menstrual	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	mot reported	103
										bleeding (n/a - Not Recovered/Not Resolved -)	1{DF} - Intramuscular])		
EU-EC- 10010097116	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	[ERGOCALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
											Intramuscular])		\perp

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											Intramuscular])		
EU-EC- 10010097150	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (3d - Recovered/Resolved -), Chest pain (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Dyspnoea (3d - Recovered/Resolved -)			
EU-EC- 10010097153	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010097168	22/09/2021	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 - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010097185	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ZINC GLUCONATE] (C - n/a - n/a - [n/a - n/a - n/a])	- ICS
EU-EC- 10010097207	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010097223	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal pain (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Lymphadenopathy (n/a - Recovering/Resolving -), Photophobia (n/a - Recovering/Resolving			
EU-EC- 10010097227	22/09/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	IC
EU-EC- 10010097233	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Neuralgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	IC
EU-EC- 10010097240	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cyst (24d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	IC
EU-EC- 10010097452	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeling hot (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Influenza (n/a - Unknown -), Injection site swelling (n/a - Unknown -), Menstrual discomfort (n/a - Unknown -),			
EU-EC- 10010097544	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (n/a - Unknown -) Axillary pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	IC

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				Area						Recovering/Resolving - Other Medically Important Condition), IgA nephropathy (n/a	1{DF} -		
										- Not Recovered/Not	indaniuscular])		
EU-EC- 10010098313	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10010098323	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Thrombocytopenic purpura (27d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010098396	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiovascular disorder (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (9d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Cough (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dysphagia (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Malaise (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nasal congestion (9d			
										- Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pericarditis (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Respiratory disorder (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Tachypnoea (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010098509	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (5h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - n/a])	Not reported	ICSR
EU-EC- 10010098598	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010098707	22/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10010099127	22/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Unknown - Other Medically Important Condition),			
	22/02/5					42 :=				Malaise (n/a - Unknown - Other Medically Important Condition)	COMPANIE :		105-
EU-EC- 10010099356	22/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Fatigue (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

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				Area), Insomnia (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -	- COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
)			
EU-EC- 10010100339	22/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (30min - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010100682	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved -), Lymphadenopathy	1{DF} - n/a])		
										(n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010100735	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - n/a - n/a])	ICSR
										Malaise (3d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (1d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -			
EU-EC- 10010100774	22/09/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Cardiovascular disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010101603	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Contusion (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Heavy menstrual bleeding (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Immune thrombocytopenia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Mouth haemorrhage			
										(n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Petechiae (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010101993	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea at rest (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Hospitalisation, Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010101998	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
										Myalgia (3d - Recovered/Resolved -), Nausea (3d -			
										Recovered/Resolved -), Vision blurred (3d - Recovered/Resolved -)			
EU-EC- 10010102012	22/09/2021	Spontaneous			Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010102057	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10010102471	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
), Pain in extremity (n/a - Recovering/Resolving -)	Intramuscular])		
EU-EC- 10010102499	22/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Migraine (n/a - Recovering/Resolving -), Vertigo (n/a - Recovering/Resolving			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10010102509	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010102568	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a -	Not reported	ICSR
EU-EC-	22/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Diarrhoea (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR

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10010102620			Healthcare Professional		available	Years				Unknown -), Nausea (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a		
										Pyrexia (n/a - Unknown -)	- n/a])		
EU-EC- 10010102633	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	ICS
EU-EC- 10010102636	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICS
EU-EC- 10010102655	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immune thrombocytopenia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICS
										Petechiae (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010102658	22/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSI
										Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a -	Intramuscular])		
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010102755	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										-), Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not			
										Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving			
EU-EC- 10010103167	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Migraine (n/a - Not Recovered/Not Resolved -), Nausea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	HYDROCORTISONE [HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - Rash - n/a - [n/a - n/a	ICSF
										Unknown -), Papilloedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])	- n/a])	
										Tinnitus (n/a -			
EU-EC- 10010103220	22/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Unknown -) Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
EU-EC- 10010074351	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
), Vaccination site pain (1d - Recovered/Resolved -			
EU-EC-	21/09/2021	Spontaneous	Non Healthcare	European	Not		Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

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			Professional	Area						Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	- COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010074497	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye pruritus (n/a - Recovering/Resolving -), Eye swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010074511	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10010074562	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
EU-EC-	21/09/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Not Resolved -) Asthma (n/a - Not	Intramuscular]) COMIRNATY	Not reported	ICSR
10010075842			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]),		
											COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10010075861	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Limb discomfort (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010075923	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010075925	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010075926	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving			

										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010076180	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Nausea (n/a - Not Recovered/Not Resolved -),	immunisation - n/a - [n/a - n/a - n/a])		
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Syncope (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010076186	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	XOLAIR [OMALIZUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Pyrexia (n/a - Recovering/Resolving -), Vertigo (n/a -	n/a - n/a])		
EU-EC-	21/09/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovering/Resolving -) Presyncope (n/a -	COMIRNATY	Not reported	ICSR
10010076228	21/09/2021	Spontaneous		Economic Area	available	Years	Specified	remale	No	Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSN
EU-EC- 10010076440	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010076577	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pain in extremity (1d - Recovered/Resolved - Other Medically Important Condition)	antianuscular j		
EU-EC- 10010076659	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema multiforme (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular])	AERIUS [DESLORATADINE] (C - Rhinitis allergic - n/a - [n/a - n/a - n/a])	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a -	antianuscular j)		
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010076744	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ear pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
										Oropharyngeal pain (n/a - Unknown -)	n/a - Intramuscular])		
EU-EC- 10010076746	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Leukopenia (n/a - Unknown -), Rash rubelliform (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010076774	21/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Purpura (n/a - Not Recovered/Not	Subcutaneous]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
10010076774			Professional		avaliable	Tedis	Specified			Resolved -)	- COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10010076784	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving -)	Intramuscular])		
EU-EC- 10010076812	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Not Recovered/Not Resolved -), Pericardial disease	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved -),	1{DF} - Intramuscular])		

										ng report			
										Recovered/Not Resolved -)			
EU-EC- 10010077103	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved -), Vasculitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10010077395	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown -) Chest pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving -), Pain in extremity (n/a			
										Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10010077720	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010077750	21/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010077900	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Swelling face (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - III- defined disorder - n/a - [5d - 3{DF} - n/a]),	ICSF
										Unknown - Other Medically Important Condition)	.3mL - n/a])	[CHLORPHENAMINE] (C - III-defined disorder - n/a - [n/a - 1{DF} - n/a]),	
												[CYCLIZINE] (C - III- defined disorder - n/a - [28d - 1{DF} - n/a]), [SODIUM	
												CROMOGLICATE] (C - III-defined disorder - n/a - [28d - 4{DF} - n/a])	
EU-EC- 10010078047	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -)	- n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010078049		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010078052	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved -), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSE
EU-EC-	21/09/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Presyncope (n/a -	COMIRNATY	Not reported	ICSF
10010078054				Economic Area	available	Years				Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10010078058	21/09/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSE
EU-EC- 10010078292	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSF
										Headache (n/a - Recovered/Resolved -)	Intramuscular])		
EU-EC- 10010078544	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC-	21/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No) Myopericarditis (n/a -	COMIRNATY	Not reported	ICSF
10010078606			Healthcare Professional	Economic	available	Years				Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10010078751	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

											- n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10010078895	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (n/a - Not Recovered/Not Resolved -),			
										Injection site warmth (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010078967	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	RELVAR ELLIPTA 92 MICROGRAMS/22 MICROGRAMS INHALATION POWDER, PRE-DISPENSED	ICSR
										Recovered/Resolved -), Pain in extremity (3d		[FLUTICASONE FUROATE, VILANTEROL] (C - Hypersensitivity - n/a - [n/a - 1{DF} -	
										- Recovered/Resolved -)		n/a]), [DESLORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a])	
EU-EC- 10010078970	21/09/2021	Spontaneous	Non Healthcare Professional		Not available	l	Not Specified	Female	No	Menstruation irregular (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S	COLLETT [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										,	Intramuscular])	[ATOMOXETINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]),	
												[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a]),	
												[VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010079418	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, ou						Headache (n/a - Recovered/Resolved -),	n/a - n/a])		
										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10010079641	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dysmenorrhoea (n/a - Recovering/Resolving -),	applicable - [n/a - n/a])		
										Heavy menstrual bleeding (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			

										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010079734	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Resolved -), Malaise (n/a - Recovering/Resolving	1{DF} - n/a])		
										-), Nausea (n/a - Recovering/Resolving			
EU-EC- 10010079863	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Malaise (1d - Recovered/Resolved -			
EU-EC- 10010080009	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSF
										Headache (n/a - Unknown -), Nausea (n/a -	- [n/a - n/a - Intramuscular])		
										Unknown -), Pelvic pain (n/a - Recovering/Resolving			
										Somnolence (n/a - Unknown -)			
EU-EC- 10010080012	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[SOMATROPIN] (C - n/a - n/a - [n/a - n/a - n/a])	
										Chest pain (n/a - Unknown -),	Intramuscular])		
										Influenza like illness (n/a - Not Recovered/Not Resolved -),			
										Nasal congestion (n/a - Unknown -),			
										Oropharyngeal pain (n/a - Unknown -),			
										Pain (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -)			
EU-EC- 10010080210	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	Not reported	ICSF
										Dizziness (n/a - Recovered/Resolved -),	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S		
										Malaise (n/a - Recovered/Resolved -),	- COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
										Nausea (n/a - Recovered/Resolved -	-,		
EU-EC- 10010080347	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Depressed level of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Vomiting (0d - Recovered/Resolved -			
EU-EC- 10010080353	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Recovering/Resolving - Other Medically Important Condition),			

										ng report			
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010080491	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]),	Not reported	ICSR
										,	[NOT AVAILABLE] (S - n/a - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010080672	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
										-), Thirst (n/a - Recovering/Resolving	Intramuscular])		
EU-EC- 10010080922	21/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (29d - Not Recovered/Not Resolved -),		[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS]	ICSR
										Breast mass (n/a - Not Recovered/Not Resolved -),	- [n/a - n/a - Intramuscular])	(C - Contraception - n/a - [n/a - n/a - n/a])	
										Breast pain (n/a - Not Recovered/Not Resolved -),			
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010080945	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[DESOGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]),	ICSR
										Headache (4d - Recovered/Resolved -)	Intramuscular])	[PHLEUM PRATENSE (225)] (C - Seasonal allergy - n/a - [n/a - n/a - n/a])	
EU-EC- 10010081038	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010081289	21/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										(n/a - Unknown -), Ligament sprain (n/a	n/a - n/a])		
EU-EC- 10010081317	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Unknown -) Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010081401	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenopia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
										Eye pain (n/a - Recovered/Resolved -),	Intramuscular])		
										Head discomfort (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -), Photophobia (n/a -			
										Recovered/Resolved -), Visual impairment			
EU-EC-	21/09/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	(n/a - Recovered/Resolved -) Chills (n/a -	COMIRNATY	Not reported	ICSR
10010081989			Healthcare Professional	Economic	available	Years	Specified			Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	,	
										Headache (n/a - Recovered/Resolved -),			
										Pyrexia (n/a -			

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EU-EC-	21/09/2021	Spontaneous		European	Not available	12-17	Adolescent	Female	No	Recovered/Resolved -) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR
10010082099			Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved -), Injection site pain (n/a - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010082119	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (2mo - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEMIDDEL [NOT AVAILABLE] (C - n/a - Drug withdrawn - [n/a - n/a - n/a])	. ICSR
										Menstrual disorder (2mo - Recovered/Resolved -			
EU-EC- 10010082631	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important			
										Condition), Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010082642	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010082651	21/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010082835	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010083016	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiac disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										stimuli (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010083198	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMENATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ALLERGEN EXTRACT FROM POLLEN OF DACTYLIS GLOMERATA, ANTHOXANTHUM ODORATUM, LOLIUM PERENNE, POA PRATENSIS AND PHLEUM PRATENSE, DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., ANTHOXANTHUM ODORATUM L., LOLIUM PERENNE L., POA PRATENSIS L., GRASS POLLEN ALLERGEN EXTRACT FROM COCKSFOOT , SWEET VERNAL GRASS , RYE GRASS , MEADOW	ICSR

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												(C - n/a - n/a - [n/a - n/a - n/a]),	
												[AZELASTINE HYDROCHLORIDE, FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a -	
EU-EC- 10010083206	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematuria (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	HUMIRA SOLUTION FOR INJECTION IN PRE- FILLED SYRINGE [ADALIMUMAB] (C - n/a	ICSR
										Condition)		- n/a - [n/a - n/a - Subcutaneous])	
EU-EC- 10010083312	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Fall (0d - Recovered/Resolved - Other Medically Important Condition),	n/a - Intramuscular])		
										Feeling abnormal (0d - Recovered/Resolved - Other Medically Important Condition),			
										Gaze palsy (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypoaesthesia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Musculoskeletal stiffness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral circulatory failure (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition),			
										Transient ischaemic attack (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010083325	21/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[FERROUS SULFATE] (C - Blood iron decreased - n/a - [n/a - n/a - n/a])	ICSR
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a - n/a])		
										Pain in extremity (n/a			
										Recovering/Resolving - Other Medically Important Condition), Tremor (n/a -			
1	I	I	I					I	I	(.,, a	l		

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										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010083347	21/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Fall (0d - Recovered/Resolved - Other Medically Important Condition),	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
										Hypotension (n/a - Unknown -),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Pallor (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010083607	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010083645	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epstein-Barr virus infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
EU-EC- 10010083716	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010083749	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in jaw (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				Alea						,	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010083818	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICSF
EU-EC- 10010083825	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -), Blood pressure	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	Not reported	ICSF
										decreased (n/a - Recovered/Resolved -),	1{DF} - Intramuscular])		
										Malaise (n/a - Recovered/Resolved -),			
										Tinnitus (n/a - Recovered/Resolved -			
EU-EC- 10010083833	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
EU-EC- 10010083834	21/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Type IV hypersensitivity reaction (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010083854	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Phlebitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
EU-EC-	21/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Influenza like illness	Intramuscular]) COMIRNATY	Not reported	ICSF

EU-EC- 10010084706 21/09/2021 Spontaneous Non Healthcare Economic Professional Area Economic	J.11.2022 1	2.13							Kun Lin	e Listii 	Recovering/Resolving	immunisation - Not applicable - [1d -		
21-09-2023 Spentamental Process Part											,	1{DF} -		
1,092021 Southmose Professional Area P		21/09/2021	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
21/09/2021 Southamesca Formal Southam), Headache (n/a -			
21/09/2021 Sportaneous Non European Not Correct Professional Non Not Correct Professional Non Not Non Not Non Not Non Not Non Not Non Not Non Non Not Non), Hypotension (n/a -			
), Nausea (n/a -			
1,109/2021 Sportaneous None Intelligence Professional		21/09/2021	Spontaneous	Healthcare	Economic				Female	No	Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
ELI-EC 21,09/2021 Sportaneous Non European Not Real		21/09/2021	Spontaneous	Healthcare	Economic				Female	No	Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICS
EU-EC- 10010084996 2 1/99/2021 Sportaneous Non Hoom Heidthrare Professional Profess											Recovered/Not	applicable - [n/a -		
EL-LEC- 10010094762 21/09/2021 Spontaneous Non European Not Healthcare Economic Available Professional Area Not reported 12-17 Not Premaic Id- Recovered/Not Resolved -). Professional Area Not Recovered/Resolved - Not R											Recovered/Resolved -			
EL-EC- 10010084762 21/09/2021 Spontaneous Non Healthrane Economic Professional Area Not reported (19- Recovered/Resolved - 10010084762) 21/09/2021 Spontaneous Non Healthrane Economic Professional Area Not reported (19- Recovered/Resolved - 10010084904)											Recovered/Not			
EU-EC- 10010984762 21/09/2021 Spontaneous Non Healthcare Economic Professional Area Not Healthcare Recovered/Resolved - Non Healthcare Recovered/Resolved - Non Healthcare Recovered/Resolved - Non Healthcare Recovered/Resolved - Non Non Non Recovered/Resolved - Non Non Non Non Non Non Recovered/Resolved - Non Non Non Non Recovered/Resolved - Non											Recovered/Not			
Professional Pro											Recovered/Resolved -			
EU-EC- 10010084904 21/09/2021 Spontaneous Non Healthcare 10010084904 21/09/2021 Spontaneous Non Healthcare 10010084904 21/09/2021 Spontaneous Non Healthcare 10010086792 21/09/2021 Spontaneous Non Healthcare 10010086894 21/09/2021 Spontaneous Non Healthcare 10010086994 21/09/2021 Spontaneous Non Healthcare 10010086994 21/09/2021 Spontaneous Non Non Healthcare 10010086994 21/09/2021 Spontaneous Non		21/09/2021	Spontaneous	Healthcare	Economic				Female	No	Recovered/Resolved -), Myalgia (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10010086894 EU-EC- 10010086884 EU-EC- 100100868864 EU-EC- 10010086864 EU-EC- 100100868864 EU-EC- 100100868864 EU-EC- 10010		21/09/2021	Spontaneous	Healthcare	Economic			Adolescent	Female	No	Chills (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S		ICS
EU-EC- 10010086792 21/09/2021 Spontaneous Professional EU-EC- 10010086864 21/09/2021 Spontaneous Non Healthcare Professional Secure Professional EU-EC- 10010086864 21/09/2021 Spontaneous Non Healthcare Professional Secure Prof											Recovered/Resolved -	applicable - [n/a - .3mL -	FORMOTEROL FUMARATE DIHYDRATE PH.EUR.] (C - n/a -	
EU-EC- 10100086792 Z1/09/2021 Spontaneous Professional Professional Secure Recovered Resolved - Disabling), Vomiting (1d - Recovered/Resolved - Disabling), Vomiting (1d - Recovered/Resolved - Disabling), Vomiting (1d - Recovered/Resolved - Disabling), Vomiting (1d - Recovering/Resolved - Disabling), Recovering/Resolving - Disabling), Professional Recovered/Resolved - Disa											Recovered/Resolved -		n/a]), [EBASTINE] (C - n/a -	
EU-EC- 10010086792 21/09/2021 Spontaneous Non Healthcare Professional Realthcare Professional Realthca											Recovered/Resolved - Disabling),			
Professional Area Professional	EU-EC-	21/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Recovered/Resolved - Disabling)	COMIRNATY	Not reported	ICSI
- Disabling), Pain (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Recovering/Resolving - Disabling), Syncope (n/a - Recovering/Resolving - Disabling) Syncope (n/a - Recovering/Resolving - Disabling) EU-EC- 10010086864 Specified Professional Foressional Fo	10010086792		·	Healthcare	Economic	available	Years				Recovering/Resolving - Disabling),	- COVID-19 immunisation - Not	·	
EU-EC- 10010086864 Variable											- Disabling),			
EU-EC- 10010086864 Recovering/Resolving - Disabling), Rash (n/a - Not Recovered/Not Resolved - Disabling), Syncope (n/a - Recovering/Resolving - Disabling), Syncope (n/a - Recovering/Resolving - Disabling) Disabling) TOZINAMERAN Not reported Not reported Years Specified No Dizziness (2d - Recovered/Resolved - Other Medically Other Medically COVID-19											Recovering/Resolving - Disabling),			
EU-EC- 10010086864 Spontaneous Non Healthcare Professional Economic Professional Professional											Recovering/Resolving - Disabling),			
EU-EC- 10010086864 Spontaneous Non Healthcare Professional Economic Economic Non Not 12-17 Not Male No Dizziness (2d - Recovered/Resolved - [TOZINAMERAN] (S - COVID-19											Recovered/Not Resolved - Disabling), Syncope (n/a -			
		21/09/2021	Spontaneous	Healthcare	European				Male	No	- Disabling) Dizziness (2d - Recovered/Resolved -	[TOZINAMERAN] (S	Not reported	ICSI
tps://dap.ema.europa.eu/analytics/saw.dll?Go					Area									50/

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EU-EC- 10010087(21/09/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (2300min - Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (2300min - Recovered/Resolved - Other Medically Important Condition), Palpitations (2300min - Recovered/Resolved - Other Medically Important Condition), Pharyngeal oedema (2300min - Recovered/Resolved - Other Medically Important Condition), Swollen tongue (2300min - Recovered/Resolved - Other Medically Important Condition), Urticaria (2300min - Recovered/Resolved - Other Medically Important Condition), Urticaria (2300min - Recovered/Resolved - Other Medically Important Condition), Amenorrhoea (n/a - Unknown -)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional	Area							- COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 100100873	21/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -) Asthenia (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported Not reported	ICSR
EU-EC- 100100878		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 100100878	394	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Dizziness (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 100100878		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 -	Not reported	<u>ICSR</u>

											Unknown - [n/a - 1{DF} - n/a])		
EU-EC- 10010087899	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (9d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010087902	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Anxiety (n/a - Recovering/Resolving -), Respiratory rate increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular]),	Not reported	ICSR
											[METHYLPHENIDATE HYDROCHLORIDE] (S - Attention deficit hyperactivity disorder - Dose not changed - [n/a - 72mg - Oral])		
EU-EC- 10010087903	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (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- 10010087917	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10010087918	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -), Vaccination site erythema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[TERBUTALINE SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC- 10010087921	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Not Resolved -)			
EU-EC- 10010087934	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DESOGESTREL] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10010087935	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Diarrhoea (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - Intramuscular])		
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010087939	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	[CLOBETASOL PROPIONATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]),	ICSR
										Dizziness (n/a - Recovering/Resolving -)	Unknown - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	

												[FEXOFENADINE HYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a - Oral])	
EU-EC- 10010087941	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICS
										-), Headache (n/a - Recovering/Resolving			
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10010087942	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (4d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Feeling hot (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - Intramuscular])		
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
FIL FO	24 (00 (2024					12.17				Nasopharyngitis (n/a - Not Recovered/Not Resolved -)	CONTRACTO		1000
EU-EC- 10010087945	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010087946	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Male	No	Urticaria (2d - Recovered/Resolved -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010087948	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010087958	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010087959	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 1{DF} - n/a])	Not reported	ICSF
), Pyrexia (2d - Recovered/Resolved -			
EU-EC- 10010088069	21/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010088575	21/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (1d - Recovered/Resolved -), Inappropriate	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [11d - .3mL -	Not reported	ICSR
										schedule of product administration (n/a - Recovered/Resolved -)	Intramuscular])		
EU-EC- 10010088652	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (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- 10010088653	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved -			

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										Headache (n/a - Recovered/Resolved -			
										Myalgia (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Weight decreased (n/a - Recovered/Resolved -			
EU-EC- 10010088694	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010088941	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010089271	21/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunication - Not	Not reported	ICSR
										Pyrexia (2d - Recovered/Resolved -), Vomiting (2d -	applicable - [n/a - .3mL - Intramuscular])		
EU-EC-	20/00/2021	Canadanasia	Nan	F	Net	12.17	Nat	Famala	Na	Recovered/Resolved -	COMIDNATY	Not year arted	ICCD
10010060118	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
), Malaise (4d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -)			
EU-EC- 10010060444	20/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010060701	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown -), Headache (n/a - Not			
										Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not			
										Resolved -), Pain in extremity (n/a - Not Recovered/Not			
EU-EC-	20/09/2021	Spontaneous		European	Not	12-17	Not	Male	No	Resolved -) Disturbance in	COMIRNATY	AERIUS	<u>ICSR</u>
10010060751			Healthcare Professional	Economic Area	available	Years	Specified			attention (n/a - Recovering/Resolving -), Dyspnoea (n/a -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DESLORATADINE] (C - n/a - n/a - [n/a - n/a - Oral]), [MONTELUKAST,	
										Recovering/Resolving -),		MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Educational problem (n/a - Recovering/Resolving -),		[VITAMIN D] (C - n/a - n/a -)	
										Headache (n/a - Recovering/Resolving -),			

										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010060766	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010060835	20/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Faeces pale (n/a - Unknown -), Feeling cold (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a -			
										Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically			
										Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010062101	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010062202	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010062387	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovering/Resolving -), Dizziness (17d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Not Resolved -), Fatigue (18d -			
										Recovering/Resolving -), Headache (18d - Not Recovered/Not			
										Resolved -), Influenza (18d - Recovering/Resolving			
										Lymphadenopathy (5d - Recovering/Resolving -),			
										Pyrexia (18d - Recovering/Resolving -),			
										Rash (5d - Recovering/Resolving -)			
EU-EC- 10010062492	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010062682	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010062852	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Appendicitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010062941	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010063234	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pain in extremity (2d - Recovering/Resolving -), Pyrexia (2d - Recovering/Resolving -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S	Not reported	ICSF

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										 Somnolence (2d - Recovering/Resolving -)	- Immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10010063476	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash pruritic (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010063545	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010064607	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010064881	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010065121	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (1d - Recovering/Resolving - Other Medically Important Condition), Hemiparesis (1d - Recovering/Resolving - Other Medically Important Condition), Syncope (1d - Recovering/Resolving - Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010065436	20/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aortic valve incompetence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tricuspid valve incompetence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tricuspid valve incompetence (n/a - Unknown - 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- 10010065697	20/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Photopsia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -			

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EU-EC- 10010066287	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis atopic (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[BUDESONIDE] (C - Asthma - n/a - [8y - 200ug - Respiratory (inhalation)]), [CETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [8y - 5mg - Oral])	ICSF
EU-EC- 10010066338	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (3d - Recovered/Resolved - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010066467	20/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
10010066483	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010066527	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Heavy menstrual bleeding (31d - Recovered/Resolved -), Menstrual disorder (1mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED O.A.C. [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10010067004	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Dose not changed - [23d - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010067076	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (1d - Recovered/Resolved -), Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010067095		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010067127		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Groin pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010067375	20/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Blood pressure fluctuation (n/a - Recovering/Resolving - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Hypotension (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF

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										Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Radial pulse abnormal			
										Recovering/Resolving - Other Medically Important Condition),			
										Shock (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010067382	20/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Eye movement disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010067393	20/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Pyrexia - n/a - [n/a - n/a - n/a])	ICSR
										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010067753	20/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cytomegalovirus infection (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Infectious mononucleosis (n/a - Unknown -)			
EU-EC- 10010067766	20/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (32min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Bradycardia (32min - Recovered/Resolved - Other Medically Important Condition),	n/a - Intramuscular])		

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										Fall (32min - Recovered/Resolved -),			
										Feeling abnormal (32min - Recovered/Resolved -),			
										Heart rate decreased (32min - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (32min - Recovered/Resolved -),			
										Presyncope (32min - Recovered/Resolved -			
EU-EC- 10010068024	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Patigue (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- 10010068156	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site movement impairment (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Diarrhoea (2d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -),			
										Pain in extremity (2d - Recovered/Resolved -)			
EU-EC- 10010068414	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	SHIFT [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Arthralgia (5d - Recovered/Resolved -),	- [n/a - n/a - Intramuscular])	TOCOPHEROL [TOCOPHEROL] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Arthralgia (n/a - Unknown -), Back pain (n/a -		[COD-LIVER OIL] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Unknown -), Bedridden (n/a - Unknown -),		[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Dysmenorrhoea (n/a - Unknown -),		[FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - Oral]),	
										Fatigue (n/a - Unknown -),		[LEMON FLAVOUR] (C -	
										Headache (n/a - Unknown -), Nausea (n/a -		n/a]), [RETINOL PALMITATE] (C - n/a - n/a - [n/a -	
										Unknown -), Pain in extremity (5d		n/a - n/a]), [TRIGLYCERIDES	
										- Recovered/Resolved -), Pain in extremity (n/a		MEDIUM CHAIN] (C - n/a - n/a - [n/a - n/a - n/a]),	
EU-EC-	20/00/2021	Coontangeus	Non	Furancan	Not	12-17	Not	Famala	No	- Unknown -)	COMIRNATY	[VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICCD
10010068422	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010068869	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	n/a - n/a])		
EU-EC- 10010068926			Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (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- 10010069263	20/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010069286	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (5d - Recovered/Resolved - Other Medically Important Condition), Pain (5d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Vomiting (5d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010069436	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eyelid oedema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010069457	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010069506	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovered/Resolved -), Rash morbilliform (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010069525	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Hypotension (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSI
										Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not			
EU-EC- 10010069571	20/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Arthralgia (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving - Recovering/Resolving - Recovering/Resolving - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF

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