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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10010761914	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
	25/44/2024					12.17				Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMPNATA		TOOD
EU-EC- 10010761953	25/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Muscle spasticity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Muscle twitching (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Presyncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling),			
										Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10010761998	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Injection site pain (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not			

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										Resolved -), Myalgia (n/a - Not Recovered/Not			
										Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010761999	25/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Vaginal discharge (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010762229	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010762780	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Albumin CSF increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<u>ICS</u>
										CSF protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Daydreaming (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010762834	25/11/2021	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	ICS
EU-EC- 10010762956	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010762963	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010763076	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (n/a - Unknown - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
										Headache (n/a - Recovered/Resolved -),	n/a - n/a])		
										Hepatic enzyme increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hypophagia (n/a - Unknown -),			
										Liver disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			

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										Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Stomatitis (n/a - Unknown -),			
										White blood cell count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010763092	25/11/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (48h - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Nausea (48h - Recovering/Resolving - Other Medically Important Condition),	Intramuscular])		
										Sensation of foreign body (48h - Recovering/Resolving - Other Medically Important Condition),			
										Vertigo (48h - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (48h - Recovering/Resolving - Other Medically Important Condition)			1000
EU-EC- 10010763093	25/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
										Blood pressure increased (14min - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fall (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Restlessness (35min			
EU-EC-	25/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Headache (1h -	COMIRNATY	Not reported	ICSR
10010763096		,	Professional		available	Years	Specified			Recovered/Resolved -), Syncope (1h - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	,	
EU EC	25/44/2021	Cnortes	Lloolth a - ···	Nor	Not	12.17	Not	Formal :	Ne	- Other Medically Important Condition)	Intramuscular])	Not reported	ICCD
EU-EC-	25/11/2021	Spontaneous	nealthcare	Non	Not	12-17	INOT	Female	No	Chest discomfort	COMIRNATY	Not reported	<u>ICSR</u>

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10010763104			Professional	European Economic Area	available	Years	Specified			(n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010763166	25/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY	Not reported	ICSI
										Costochondritis (n/a - Recovering/Resolving	, , , , ,		
EU-EC-	25/11/2021	Cnontonoous	Licolthanus	Non	Not	12.17	Not	Famala	No	- Other Medically Important Condition)	COMIRNATY	Not reported	ICC
10010763178	25/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICS</u>
										Fall (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Headache (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010763209	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
										Blood pressure abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a - Intramuscular])		
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Sensitive skin (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- L0010763275	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Anaphylactic shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Intramuscular])		
										Asthenia (n/a - Not Recovered/Not Resolved -),			
										Bronchospasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Cough (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Hypokinesia (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010763279	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS

EU-EC- 10010763288	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Stridor (n/a - Unknown - Other Medically Important Condition), Stridor (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010763458	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovered/Resolved -), COVID-19 immunisation (n/a - Recovered/Resolved -), Constipation (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010763522	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Head discomfort (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR

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										Resolved -), Paraesthesia (n/a - Not Recovered/Not			
EU-EC- 10010763642	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) 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- 10010763645	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010763909	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved -), Menstruation delayed (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Myalgia (7d - Recovered/Resolved	1(0)		
EU-EC- 10010764042	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	-/		
EU-EC- 10010764046	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010764169	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010764763	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Orchitis (n/a - Recovering/Resolving - Other Medically Important Condition)	- COVID-19	Not reported	ICSR
EU-EC- 10010764851	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} -	Not reported	ICSR
										Urticaria (n/a - Not Recovered/Not Resolved -),	Intramuscular])		
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010765090	25/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dissociative disorder (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010765091	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Unknown -)		Not reported	ICSR
EU-EC- 10010765237	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010765268	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Cough (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			

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										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovered/Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010765364	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Not Recovered/Not Resolved -)	n/a - Intramuscular])		
EU-EC- 10010765405	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthma exercise induced (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010765423	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010765431	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved -), Palpitations (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC-	25/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	-) Heavy menstrual	COMIRNATY	Not reported	ICSR
10010765456			Healthcare Professional	Economic Area	available	Years				bleeding (2d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010765462	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vertigo (17d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010765505	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010765626	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010765685	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010765702	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breast cyst (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Resolved -), Mastitis (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010765871	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010765927	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dry skin (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Menstruation delayed (n/a - Recovered/Resolved -),	applicable - [1d - 1{DF} - Intramuscular])		
										Vaccination site pain (n/a - Recovered/Resolved			
EU-EC- 10010765947	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - 2{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010766267	25/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010766442	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Headache (2d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Myalgia (3d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
EU-EC-	25/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Pyrexia (2d - Recovered/Resolved -) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICS
10010767036	23/11/2021	Sportalieous	Healthcare Professional	Economic	available	Years	Specified	remale	INO	Not Recovered/Not Resolved -), Fatigue (7d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	10.5
EU-EC- 10010767075	25/11/2021	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 -	Not reported	ICS
EU-EC- 10010767266	25/11/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR.] (C - Asthma - n/a - [n/a - n/a - n/a]),	ICS
												[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	
EU-EC- 10010767447	25/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010767701	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Fatique (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Recovered/Resolved -), Headache (2d -	1{DF} - n/a])		
										Recovered/Resolved -), Injection site pain			
										(2d - Recovered/Resolved -),			
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (2d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved			

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										Pyrexia (2d - Recovered/Resolved			
EU-EC- 10010768316	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebral venous sinus thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010768795	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tonsillar inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010768804	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010768809	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010768811	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010768815	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010768818	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010768959	25/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010735218	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735228	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735291	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735348	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site swelling (41d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735383	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR

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EU-EC- 10010735428	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Headache (2d - Recovering/Resolving -), Influenza (1d - Recovering/Resolving -), Limb discomfort (0d - Not Recovered/Not Resolved -), Nausea (1d - Not Recovered/Not	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010736211	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Headache (2d - Recovered/Resolved -), Lymphadenopathy (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010736370	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010736477	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (14d - Not Recovered/Not Resolved -), Injection site pain (14d - Not Recovered/Not Resolved -), Malaise (14d - Not Recovered/Not Resolved -), Rash (2d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736788	24/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Hepatitis (17d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (6d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010737430	24/11/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Vomiting (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010737475	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Not Recovered/Not Resolved -), Fatigue (1d - Not Recovered/Not Resolved -), Influenza (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010737478	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (1d - Recovered/Resolved -), Limb discomfort (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010738000	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
EU-EC- 10010738036	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (63d - Recovered/Resolved -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
EU-EC- 10010738076	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovering/Resolving -), Dizziness (0d - Recovering/Resolving -), Fatigue (0d - Recovering/Resolving -), Headache (0d - Recovering/Resolving -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF

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										Limb discomfort (1d - Recovering/Resolving			
										Nausea (0d - Recovering/Resolving -),			
										Pyrexia (0d - Recovering/Resolving -)			
EU-EC- 10010738087	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovered/Resolved -), Feeling hot (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10010738128	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010738158	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010738192	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Unknown -), Headache (0d - Unknown -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010738202	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Unknown -) Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010738208	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Limb discomfort (1d - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved -), Tachycardia (n/a - Recovered/Resolved -)			
EU-EC- 10010738229	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010738254	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Dizziness (3d - Not Recovered/Not Resolved -), Vomiting (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010738315	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Cough (4d - Recovering/Resolving -), Headache (3d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (3d - Recovered/Resolved -), Pyrexia (1d -			
EU-EC-	24/11/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Resolved -) Fatigue (1d -	COMIRNATY	Not reported	ICSR
10010738318			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -), Headache (1d - Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Injection site pain (4d - Recovering/Resolving -),			
										Myalgia (2d - Recovering/Resolving -)			
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Injection site pain	COMIRNATY	Not reported	<u>ICSR</u>

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10010738399			Healthcare Professional		available	Years				(1d - Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Pyrexia (1d - Recovering/Resolving -)	1,01,7		
EU-EC- 10010738456	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (n/a - Recovering/Resolving -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										reaction (7d - Recovering/Resolving -)	1,01,7		
EU-EC- 10010738565	24/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (4d -	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional	Area						Recovered/Resolved	- Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010738699	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Myalgia (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Recovered/Resolved -), Pyrexia (1d -	1,,,		
										Recovered/Resolved			
EU-EC- 10010738795	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -), Dizziness (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Recovering/Resolving -),	1,741,7		
										Headache (0d - Recovered/Resolved -),			
										Injection site erythema (2d - Recovered/Resolved -)			
EU-EC- 10010738832	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
										Cough (n/a - Not Recovered/Not Resolved -),	n/a - [n/a - n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010738853	24/11/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -),	n/a])		
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10010738882	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	-) Pyrexia (0d -	n/a - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10010738898	24711/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Adolescent	riale		Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICOK
EU-EC- 10010738914	24/11/2021	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 -	Not reported	ICSR
EU-EC- 10010738942	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Fatigue (1d - Recovering/Resolving -),	n/a])		
										Headache (1d - Recovering/Resolving -),			
										Malaise (1d - Recovering/Resolving -),			
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10010739019	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR

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										Injection site pain (1d - Not Recovered/Not Resolved -)	n/a - [n/a - n/a - n/a])		
EU-EC- 10010739037	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010739049	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Nausea (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010739058	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010739061	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Headache (5d - Recovered/Resolved -), Injection site erythema (8d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010739082	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010739107	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (8d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010739146	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -), Nausea (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
10010739155			Healthcare Professional	Economic Area			Adolescent		No	Feeling hot (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Limb discomfort (0d - Recovered/Resolved -), Lymphadenopathy (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010739166	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010739215	24/11/2021	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 - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010739288	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Monoparesis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010739373	24/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010739374	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Pyrexia (n/a - Recovered/Resolved	applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010740168	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically	- COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010740399	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Abdominal pain (n/a - Not Recovered/Not Resolved -), Arthralgia (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010740422	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	- COVID-19	Not reported	ICSR
EU-EC- 10010740423	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Electrocardiogram ST segment depression (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown -), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740496	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Hallucination (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740510	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740516	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [n/a -		
EU-EC- 10010740520	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740522	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Meningitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740540	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Troponin increased (n/a - Recovered/Resolved -)			
EU-EC- 10010740562	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pancreatitis (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
EU-EC- 10010740563	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematoma (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010740581	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved -),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	n/a - n/a])		
										Rhabdomyolysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site hypersensitivity (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010740629	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
EU-EC- 10010740639	24/11/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) Axillary pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional	Economic Area						Chills (n/a - Unknown -), Headache (n/a - Unknown -),	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Malaise (n/a - Unknown -), Pyrexia (n/a -			
										Unknown - Other Medically Important Condition), Vaccination site pain			
										(n/a - Unknown -), Vaccination site			

										ting report	1	ı	
										swelling (n/a - Unknown -)			
EU-EC- 10010740642	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740651	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Other])	Not reported	ICSR
										Viral myocarditis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010740652	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[COLCHICINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010740660	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740680	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (1d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740774	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010740780	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Thrombocytopenia (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- 10010740952	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Dyskinesia (25min - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Dyskinesia (50min - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Narcolepsy (n/a - Unknown - Life Threatening, Other Medically Important Condition), Paralysis (25min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										- Life Threatening, Other Medically Important Condition),			
										Paralysis (50min - Recovered/Resolved - Life Threatening, Other Medically Important Condition)			
:U-EC- .0010741216	24/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition)	- COVID-19 immunisation - n/a	Not reported	ICSR
:U-EC- .0010742292	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
										Chills (n/a - Unknown - Other Medically Important Condition),			
										Diarrhoea (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),			
										Muscle spasms (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition)			
U-EC- 0010742366	24/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition),			
31.50	24/11/2021	Sportonogue	Non	Mon	Not	12-17	Not	Fomale	No	Swelling face (1d - Recovered/Resolved - Other Medically Important Condition)	COMIDNATY	ECODEINE (C. Daia a)	ICCD
EU-EC- 1.0010742377	24/11/2021	Spontaneous		Non European Economic Area	Not available	Years	Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - Polycystic ovaries - n/a - [n/a - n/a - n/a]), [FLUOXETINE	ICSR
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),		HYDROCHLORIDE] (C - Anger - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Polycystic ovaries - n/a - [n/a - n/a	
										Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important		- n/a - n/a])	

										Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Painful respiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary embolism (1d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Supraventricular tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
EU-EC- 10010742439	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742440	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742450		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742458	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving -), Chest discomfort (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Myalgia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Neck pain (n/a - Recovering/Resolving -)			
EU-EC- 10010742475	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Troponin I increased (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742484	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Syncope (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
EU-EC- 10010742485	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Dysphonia (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Respiratory disorder (n/a - Unknown -), Throat tightness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742515	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Recovering/Resolving -), Electrocardiogram abnormal (n/a - Recovering/Resolving -), Seizure (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
EU-EC- 10010742519		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742523		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Recovered/Resolved -), Generalised tonic- donic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742543		Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742553	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute kidney injury (n/a - Recovering/Resolving - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving -), Myalgia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -), Troponin increased (n/a -			
										Recovering/Resolving -), Vomiting (n/a -			
										Recovering/Resolving -)			
EU-EC- 10010742566	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petit mal epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010742572	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye swelling (n/a - Recovering/Resolving -), Eyelids pruritus (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010742574	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-	24/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY	Not reported	ICSR
10010742584			Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010742585	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010742603	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not			
										Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010742604	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram abnormal (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742607	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Pericarditis (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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EU-EC- 10010742635	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Diarrhoea haemorrhagic (n/a - Recovering/Resolving - Other Medically Important Condition)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742650	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving Resolving - Recovering/Resolving - Recovering/Resolving - Recovering/Resolving - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742671	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742690	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010742693	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (35min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
10010743034	24/11/2021	Spontaneous	Healthcare Professional				Adolescent	Male	No	Daydreaming (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Hyporesponsive to stimuli (n/a - Recovered/Resolved -), Starring (n/a - Recovered/Resolved -)	COMIRNATY	AERIUS [DESLORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral]), [AZELASTINE HYDROCHLORIDE, FLUTICASONE PROPIONATE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - Oral]), [FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010743228	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010743231	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010743261	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010743270	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Electrocardiogram abnormal (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Myocarditis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a -			
										Unknown -), Troponin increased (n/a - Unknown -)			
EU-EC- 10010743332	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blepharospasm (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Muscle spasms (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - n/a - n/a])		
EU-EC- 10010743412	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Indamuscular J)		
EU-EC- 10010743496	24/11/2021	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 - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010743513	24/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10010743618	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (3d - Not Recovered/Not Resolved -), Headache (3d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Pyrexia (2d - Not Recovered/Not Resolved -)			
EU-EC- 10010743624	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010743638	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010743670	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010743677	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010743678	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
EU-EC- 10010743691	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown -			

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										Caused/Prolonged Hospitalisation)			
EU-EC- 10010743845	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiovascular disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010743892	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010743907	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
											COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
10010744226	24/11/2021	Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010744466	24/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010744610	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010744650	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown -), Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010744825	24/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (2d - Recovered/Resolved -), Limb discomfort (1d			
										Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved			
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	-) Fatigue (0d -	COMIRNATY	Not reported	ICSR
10010744851	2 1/ 11/ 2021	Spontaneous	Healthcare Professional	Economic	available	Years	radieseene	remare		Recovering/Resolving -), Myalgia (0d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	not reported	ICSIN
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	-) Fatigue (2d -	COMIRNATY	Not reported	ICSR
10010744852			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Headache (0d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Injection site pain (3d -			
										Recovered/Resolved -),			
										Limb discomfort (1d			
										Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10010744932	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010744933	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010744970	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR

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										Recovering/Resolving -), Nausea (1d - Recovering/Resolving			
										-)			
EU-EC- 10010744978	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010745173	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Unknown -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
										Feeling hot (0d - Unknown -), Influenza (0d -	n/a - [n/a - n/a - n/a])		
										Unknown -), Malaise (0d -			
										Unknown -), Nausea (0d - Unknown -),			
										Tachycardia (0d - Unknown -)			
EU-EC- 10010745187	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010745210	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (31d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Injection site pain (4d - Recovered/Resolved -),	n/a])		
										Limb discomfort (1d			
										Recovered/Resolved -), Lymphadenopathy			
										(20d - Not Recovered/Not Resolved -),			
										Malaise (1d - Recovered/Resolved -)			
EU-EC- 10010745324	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										Headache (1d - Not Recovered/Not Resolved -),	n/a])		
										Malaise (1d - Not Recovered/Not Resolved -)			
EU-EC- 10010745397	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										Malaise (0d - Not Recovered/Not Resolved -),	n/a])		
										Nausea (1d - Recovering/Resolving -)			
EU-EC- 10010745400	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010745409	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010745462	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010745664	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010745878	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
										Headache (1d - Recovered/Resolved -),	n/a - [n/a - n/a - n/a])		
										Injection site pain			

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										(3d - Recovered/Resolved -),			
										Limb discomfort (1d			
										Recovered/Resolved			
										Myalgia (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10010745929	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010745994	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved -),	n/a - [n/a - n/a - n/a])		
										Fatigue (0d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10010745999	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiovascular disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010746040	24/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
100107 100 10			Professional		available	loais				-), Dizziness (0d - Recovered/Resolved	- Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (0d - Not Recovered/Not Resolved -)			
EU-EC- 10010746437	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Monoplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-	24/11/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	COVID-19 (n/a -	COMIRNATY		
10010746441			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	(C - Immunisation - n/a - [n/a - 1{DF} - n/a])	
										Vaccination failure (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10010746595	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	Hospitalisation) Myocarditis (n/a -	n/a]) COMIRNATY	Not reported	ICSR
10010746596	2-1/11/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Adolescent	remare		Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	1001
EU-EC- 10010746630	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (1d - Recovered/Resolved -)	1,74 1,74])		
EU-EC- 10010746687	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010748748	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
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EU-EC- 10010749063	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Condition),	applicable - [n/a -		
										Troponin abnormal	n/a - n/a])		
										(n/a - Not Recovered/Not			
										Resolved -)			1
EU-EC- 10010749064	24/11/2021	Spontaneous	Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Pneumothorax (n/a - Recovering/Resolving	[TOZINAMERAN] (S	Not reported	ICSR
				Economic Area						- Other Medically Important Condition)	- COVID-19 immunisation - Not		
										,	applicable - [n/a - n/a - n/a])		
EU-EC-	24/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Dizziness (n/a -	COMIRNATY	Not reported	ICSR
10010749117			Professional	European Economic	available	Years	Specified			Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19		
				Area						Dyspnoea (n/a -	immunisation - Not applicable - [1d -		
										Recovering/Resolving	n/a - n/a])		
										Fatigue (n/a - Recovering/Resolving			
										-),			
										Headache (n/a - Recovering/Resolving			
										-),			
										Malaise (n/a - Recovering/Resolving			
										-),			
										Myocarditis (n/a -			
										Recovering/Resolving - Other Medically			
										Important Condition),			
										Pain (n/a -			
										Recovering/Resolving			
										Palpitations (n/a - Recovering/Resolving			
										-),			
										Pericarditis (n/a - Recovering/Resolving			
										- Other Medically Important			
										Condition),			
										Pyrexia (n/a -			
										Recovering/Resolving -),			
										Troponin increased			
										(n/a - Recovering/Resolving			
EU-EC-	24/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	-) Fatigue (n/a -	COMIRNATY	[LEVOTHYROXINE SODIUM]	ICSR
10010749130	24/11/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	remale		Recovering/Resolving	[TOZINAMERAN] (S	(C - Thyroid disorder - n/a -	1001
			Professional	Area						-),	- n/a - n/a - [n/a - n/a - n/a])	[[1]/a - 50ug - 1]/a])	
										Injection site pain (n/a -			
										Recovering/Resolving -),			
										Nasal congestion (2d			
										- Recovered/Resolved			
										-),			
										Pyrexia (2d - Recovered/Resolved			
										-),			
										Seizure (2d -			
										Recovered/Resolved - Other Medically			
										Important Condition),			
										Somnolence (2d -			
										Recovered/Resolved			
										Tremor (3d -			
										Recovered/Resolved			
EU-EC-	24/11/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Syncope (1d -	COMIRNATY	Not reported	ICSR
10010749181			Healthcare Professional	European Economic	available	Years	Specified			Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19		
				Area						Important Condition)	immunisation - Not applicable - [1d -		
EU EC	24/11/2021	Cnart	Llookh -	Nor	Not	12.17	Not	Ma!-	N	Distripose (e.f.	n/a - n/a])	Not reports -	7000
EU-EC- 10010749217	24/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving		Not reported	<u>ICSR</u>
				Economic Area						-),	- COVID-19 immunisation - Not		
										Feeling hot (n/a - Recovering/Resolving	applicable - [n/a - n/a - n/a])		
										-),	. ,,		
										Loss of consciousness (n/a -			
										Recovering/Resolving			

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FILEO	24/44/2024					10.47	N	N4-1		Important Condition)	COMPNATA	N. I I. I	Tool
EU-EC- 10010749248	24/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICS</u>
EU-EC- 10010749274	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Nausea (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Tinnitus (n/a - Recovered/Resolved -),			
EU EC	24/11/2021	Chantanaous	Llogithoogo	Non	Not	12-17	Not	Mala	No	Vision blurred (n/a - Recovered/Resolved -)	COMIDNATY	Not reported	ICC
EU-EC- 10010749283	24/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Male	No	Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICS</u>
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010749304	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										IIIrd nerve paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010749328	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICS</u>
										Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010749351	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (30min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010749356	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - n/a])	ICSF
										Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010749389		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Deep vein thrombosis (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	ICSI
EU-EC- 10010749390	24/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Monoplegia (n/a - Not Recovered/Not Resolved - Disabling,	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF

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				Economic Area						Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-	24/11/2021	Spontaneous	Hoaltheare	Non	Not	12-17	Not	Female	No	Condition), Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition) Cold sweat (n/a -	COMIRNATY	Not reported	ICSR
10010749393	24/11/2021	Spontaneous			available	Years	Specified	remale	INO	Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICOK
										Fatigue (n/a - Recovering/Resolving -), Orthostatic hypotension (n/a - Recovering/Resolving			
										-), Pallor (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving			
										- Other Medically Important Condition), Tinnitus (n/a - Recovering/Resolving -)			
EU-EC- 10010749430	24/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010749432	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	Yes	Important Condition) Angina pectoris (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac disorder (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010749470	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -)	ICSR
										Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hemiplegia (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypertension (n/a -			
										Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010749708	24/11/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved With Sequelae - Other Medically Important Condition),	.,, - ,, -,,		
										Tachycardia (n/a - Unknown - Other			

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EU-EC- 10010749714	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Medically Important Condition) COVID-19 (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010749906	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010749915	24/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Other Medically Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010749983	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010749991	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Musculoskeletal disorder (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Skin swelling (2d - Recovered/Resolved - Other Medically Important Condition),			

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										Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10010750033	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition) Muscle spasms (40min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010750275	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoacusis (n/a -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Malaise (n/a -			
										Recovering/Resolving -), Nausea (n/a -			
										Recovering/Resolving -), Pallor (n/a - Recovering/Resolving			
										-), Paraesthesia (n/a - Recovering/Resolving			
										Visual impairment			
EU-EC- 10010750291	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -) Electrocardiogram abnormal (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010750490	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Atrial fibrillation (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010750790	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fall (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR
										Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not	n/a - [n/a - 2{DF} - n/a])		
										Resolved -), Respiratory tract infection (n/a -			
EU-EC- 10010750798	24/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Vaccination site reaction (36d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
	24/11/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Chest pain (n/a -	n/a]) COMIRNATY	Not reported	ICSR
10010750873			Professional	European Economic Area	available	Years	Specified			Recovering/Resolving -), Electrocardiogram abnormal (n/a - Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Myocarditis (n/a - Recovering/Resolving			
										- Other Medically Important Condition),			

EU-EC- 10010750910		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified		No	Pneumonia (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
EU-EC- 10010750941	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	2.44.4/2024			_						- Other Medically Important Condition)			
EU-EC- 10010751070	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010751081	24/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010751088	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010751178	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010751207	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010751270	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vascular purpura (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010751340	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adult	Female	No	Acne (7d - Recovered/Resolved -), Peripheral swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010751362	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -), Immunisation reaction (n/a - Recovered/Resolved -), Varicose vein (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010751685	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (25d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[FLUTICASONE PROPIONATE, SALMETEROL] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010751762	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved -), Breast swelling (n/a - Unknown -)	- Immunisation - n/a - [n/a - n/a -	[NORETHISTERONE] (C - Dysmenorrhoea - n/a - [n/a - .35mg - n/a])	ICSR
EU-EC- 10010751901	24/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Deafness (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INVEGA [PALIPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (ADSORBED)] (C - n/a - n/a - [1d - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	

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										Recovered/Not Resolved -), Heart rate increased (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vitreous floaters (n/a - Recovered/Resolved -)		[LITHIUM] (C - n/a - n/a - [n/a - n/a - n/a - n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010752158	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -) Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010752159	24/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Aphasia (n/a - Not Recovered/Not Resolved -), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Paresis (n/a - Not Recovered/Not Resolved -), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved -), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Not Re	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010752303	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010752307	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (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- 10010752316	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Insomnia (n/a - Recovering/Resolving - Other Medically Important Condition), Panic attack (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010752338	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenopia (n/a - Unknown -), Glare (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Vomiting (n/a - Unknown -)			
EU-EC- 10010752377	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	<u>ICSR</u>
EU-EC- 10010752638	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Dizziness (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving - Recovering/Resolving - Recovering/Resolving	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),			
										Neck pain (n/a - Recovering/Resolving -), Palpitations (n/a -			
										Recovering/Resolving -), Syncope (n/a - Recovering/Resolving			
										- Other Medically Important Condition)			
EU-EC- 10010752857	24/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
				Economic Area						Recovered/Resolved -), Arthralgia (n/a -	- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Chills (n/a -	1,42 1,43)		
										Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -),			
										Lethargy (n/a - Recovered/Resolved -),			
										Myalgia (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Recovered/Resolved -),			
EU-EC-	24/11/2021	Spontaneous	Liaalthaava	Non	Not	12-17	Not	Male	No	Vomiting (n/a - Recovered/Resolved -) Bell's palsy (n/a -	COMIRNATY	Not reported	ICCD
10010753424		·	Professional	European Economic Area	available	Years	Specified			Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC- 10010753532	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important			

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										Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
EU-EC- 10010753683	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Tachycardia (n/a - Unknown - Other Medically Important Condition) Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	inidamusculai j		
										Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010753692	24/11/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a -			
EU-EC- 10010754015	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available		Not Specified	Female	No	Recovering/Resolving -) 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- 10010754224	24/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lymphadenopathy (3d - Recovered/Resolved -), Pyrexia (1d -			
										Recovered/Resolved			
EU-EC- 10010754635	24/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	remale	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010754710	24/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010754932	24/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn -	Not reported	ICSR

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EU-EC- 10010755026	24/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010755070	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010755154	24/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haemorrhage urinary tract (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (5d - Recovered/Resolved - Other Medically Important Condition) - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010755265	24/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Night sweats (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010719857		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -), Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010720000	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Autonomic dysreflexia (n/a - Recovering/Resolving - Other Medically Important Condition), Cold sweat (n/a - Recovering/Resolving - Other Medically Important Condition), Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition), Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BILASTINE] (C - n/a - n/a - [n/a - n/a - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR

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										Condition), Physical deconditioning (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Unknown -)			
EU-EC- 10010720059	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumomediastinum (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumonitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10010720156	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010720174	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Visual impairment (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10010720200	23/11/2021	Spontaneous	Healthcare Professional		Not available		Not Specified	Male	No	Lymphadenopathy (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010721136	23/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovered/Resolved -), Cold sweat (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010721280	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Unknown -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010721282		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(n/a - Unknown -) Breast swelling (n/a - Recovering/Resolving -), Gynaecomastia (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -)		Not reported	ICSR
EU-EC- 10010721283	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (2mo - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSR

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										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	n/a - [n/a - n/a - Intramuscular])		
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010721290	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
										Headache (n/a - Not Recovered/Not Resolved -), Mood swings (n/a - Not Recovered/Not Resolved -)	,	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3- ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a - [n/a - n/a - n/a - n/a)	
EU-EC- 10010721299	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 immunisation (n/a - Unknown -), Dysmenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]),	IRON [IRON] (C - n/a - n/a -	ICSF
										- Unknown -), Heavy menstrual bleeding (n/a - Unknown -),	SPIKEVAX [COVID- 19 MRNA VACCINE MODERNA (CX- 024414)] (S - Immunisation - n/a	[1/4 1/4 1/4])	
										Menstruation delayed (n/a - Recovered/Resolved -)			
EU-EC- 10010721303	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown -), Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010721306	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										(n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a			
EU-EC-	23/11/2021	Spontaneous		European	Not	12-17	Not	Female	No	- Unknown -) Headache (n/a - Not	COMIRNATY	Not reported	ICSI
10010721321			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010721322	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSF
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	Intramuscular])		
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010721324	23/11/2021	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	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010721328	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Dizziness (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	[VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Dry skin (n/a - Not Recovered/Not Resolved -),	n/a - [n/a - n/a - Intramuscular])		
										Fatigue (14d - Recovered/Resolved -),			
										Nasal congestion (n/a - Unknown -), Paraesthesia (n/a - Recovering/Resolving			
										-), Paraesthesia (n/a - Unknown -),			
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										Pruritus (n/a - Not Recovered/Not Resolved -),			
EU-EC- 10010721495	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Respiratory symptom (n/a - Unknown -) Chest pain (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Pleurisy (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010721555	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pallor (n/a - Recovered/Resolved -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010721558	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010721569	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC- 10010721707	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1min - Unknown - Caused/Prolonged Hospitalisation), Syncope (1min - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	22/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Mala	No	Hospitalisation) Chest pain (n/a -	COMIRNATY	Not reported	ICSR
10010721943	23/11/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Audiescent	riale	NO	Unknown - Life Threatening), Dyspnoea (n/a - Unknown - Life Threatening), Lymphadenopathy (n/a - Unknown -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSK
EU-EC- 10010722188		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Life Threatening) Abdominal distension (n/a - Recovering/Resolving -), Amenorrhoea (n/a - Not Recovered/Not Resolved -), Constipation (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010722603	23/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mass (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010722665	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010722675	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Feeding disorder	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										(n/a - Unknown - Other Medically Important Condition),			
										Feeling abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Somnolence (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010722679	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10010722701	23/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Erythema of eyelid (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Eye pain (n/a - Recovering/Resolving - Other Medically Important Condition),	1,40 1,40])		
										Eye swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Lacrimation increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tinnitus (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010722765	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown -), Heavy menstrual bleeding (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Polymenorrhoea (n/a - Unknown -)			
EU-EC- 10010723250	23/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving		[PYRIDOSTIGMINE] (C - Muscular weakness - n/a -	ICSR

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				Area						- Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])	[n/a - n/a - n/a])	
										Condition aggravated (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010724462	23/11/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010724523	23/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Injected limb mobility decreased (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010724547	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Mass (n/a - Recovering/Resolving -),			
										Thrombosis (n/a - Recovering/Resolving -), White blood cell			
										count decreased (n/a - Recovering/Resolving			
EU-EC- 10010724587	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Malaise (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Somnolence (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010724607	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovering/Resolving -),	- Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -), Pain in extremity	n/a])		
	22/44/2024					10.17				(n/a - Recovering/Resolving -)			1000
EU-EC- 10010724944	23/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Visual field defect (n/a - Not Recovered/Not			

										Resolved - Other Medically Important Condition)			
EU-EC- 10010725066	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Arthralgia (n/a - Recovering/Resolving -),	- COVID-19	Not reported	ICSR
										Breast pain (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Chills (2d - Recovered/Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (1d - Recovered/Resolved -),			
										Injection site pain (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (1d - Recovered/Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10010725358	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Febrile convulsion (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Area						Feeling hot (0d - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])		
										Pyrexia (0d - Recovered/Resolved -),			
										Seizure (0d - Recovered/Resolved - Other Medically Important Condition),			
										Skin ulcer (0d - Recovered/Resolved			
EU-EC- 10010725367	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010725403	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF

										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010725754	23/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	Not reported	ICSF
										Dizziness (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	[MESTRANOL, NORETHISTERONE] (S - n/a - Unknown - [n/a - n/a - n/a])		
										Feeling abnormal (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Vision blurred (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010725765	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010725772	23/11/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICS
				Economic Area						Electrocardiogram abnormal (n/a - Unknown -),	- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
	22/44/2024					10.17		-		Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMPANY		100
EU-EC- 10010725911	23/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Headache (n/a - Unknown - Other Medically Important Condition),	11/4 - 11/4])		
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash macular (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010726265	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [57d - n/a -	Not reported	ICSI
										Alopecia (n/a - Not Recovered/Not Resolved -),	Intramuscular])		
										Arthralgia (n/a - Not Recovered/Not Resolved -),			
ı										Decreased appetite			

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										(n/a - Not Recovered/Not Resolved -),			
										Diarrhoea (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010726295	23/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tourette's disorder (n/a - Recovered/Resolved With Sequelae - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL, LACTOSE, LACTOSE HYDROUS, LACTOSE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10010726394	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010726510	23/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10010726514	23/11/2021	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 - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10010726529	23/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Concomitant disease aggravated (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a -), [DIENOGEST, ETHINYLESTRADIOL] (C -	ICSR
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	,	Contraception, Dysmenorrhoea - n/a - [n/a - n/a - n/a]),	
										Fatigue (n/a - Not Recovered/Not Resolved -),		[FOLIC ACID] (C - n/a - n/a -), [VITAMIN D] (C - n/a - n/a -)	
										Headache (n/a - Recovering/Resolving -),			
										Lymphadenopathy (n/a - Recovering/Resolving -),			
										Malaise (n/a - Unknown -),			
										Neck pain (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -),			
										Pyrexia (4d - Recovered/Resolved -)			
EU-EC- 10010726552	23/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[LYMECYCLINE] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
										Lymphadenopathy (n/a - Recovering/Resolving -),	Intramuscular])		
										Pain (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010726678	23/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
FILEC.	22/11/2021	Cnort	Nan	Non	Not	12.17	Not	For:-!	NI.	Troponin increased (n/a - Unknown -)	n/a - n/a])	Not reports -	TOOS
EU-EC- 10010726710	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

								rtan Li	ilo Elo				
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not	applicable - [1d - n/a - n/a])		
										Recovered/Not Resolved - Other Medically Important Condition),			
FILES	22/11/2021		Nec	5	Net	12.17	Note	- Famela	Nic	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMPNATA	News	ICCD
EU-EC- 10010726717	23/11/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Joint swelling (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Pain in extremity (n/a - Not Recovered/Not Resolved -),	,		
										Peripheral swelling (n/a - Not Recovered/Not Resolved -),			
										Vaccination site discolouration (n/a - Not Recovered/Not Resolved -), Vaccination site			
										warmth (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010726733	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (n/a -	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
EU-EC-	23/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovering/Resolving -) Dysmenorrhoea (n/a	Intramuscular]) COMIRNATY	Not reported	ICSR
10010726777	23/11/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	remare		- Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	not reported	<u>ICSIX</u>
										Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not			
										Resolved -), Menstruation delayed (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovering/Resolving			
EU-EC- 10010726948	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available		Not Specified	Female	No	Limb discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Reflexes abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10010727244	23/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Partial seizures (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

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EU-EC- .0010727277	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	IC
EU-EC- .0010727343	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	10
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Intramuscular])		
U-EC- 0010727424	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematemesis (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn -	Not reported	
11.50	22/14/2024		No	-	Note	12.17	Note	Female	N.	Vomiting (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	[1d3mL - Intramuscular])		
U-EC- 0010727561	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	remale	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	
U-EC- 0010727813	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(545min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	
										Cough (545min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Diarrhoea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Flushing (545min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pruritus (545min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Wheezing (514min - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
J-EC- 0010727881	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
U-EC- 0010727940	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[LEVONORGESTREL] (C - n/a - n/a -), [MINERALS NOS, VITAMINS	
										-), Menstruation delayed	Intramuscular])	NOS, OMEGA-3 FATTY ACIDS] (C - n/a - n/a -), [MINERALS NOS] (C - n/a -	
										(n/a - Recovered/Resolved With Sequelae -), Pain (n/a - Unknown		n/a -), [VITAMINS NOS] (C - n/a - n/a -)	
J-EC- 0010727997	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Diarrhoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	-
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vision blurred (n/a - Unknown - Other			

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										Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC-	23/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Malaise (n/a -	COMIRNATY	Not reported	ICSR
10010728065			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010728225	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010728270	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010728298	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -), Pruritus (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010728439	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010728472	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Constipation (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Intermenstrual bleeding (n/a - Recovering/Resolving Resolving Resolvin	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	[ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - Contraception - n/a - [n/a - n/a - n/a]), [ISOTRETINOIN] (C - n/a - n/a - [n/a - n/a - n/a])	
										-)			
EU-EC- 10010728546	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010728790	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010729114	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010729223	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Syncope (50min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010729340	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Eye swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Hypersensitivity (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Important Condition),			
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Throat irritation (n/a			
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010729520	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010729550	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010729795	23/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional	Area						Fatigue (n/a - Recovering/Resolving	- Immunisation - n/a - [n/a - n/a - n/a])		
										-), Lymphadenopathy (n/a - Recovering/Resolving -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10010729857	23/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[DICYCLOVERINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										Dizziness (n/a - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])	[FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Eyelid margin crusting (n/a - Recovered/Resolved -),			
										Feeling abnormal (n/a - Recovered/Resolved -),			
										Impaired driving ability (n/a - Recovered/Resolved -),			
										Mental impairment (n/a - Recovered/Resolved - Other Medically Important			
										Condition), Movement disorder (n/a -			
										Recovered/Resolved -), Pain (n/a - Recovered/Resolved			
										-), Pyrexia (n/a - Recovered/Resolved			
										Vaccination site bruising (n/a - Recovered/Resolved			
EU-EC- 10010731139	23/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	-) Cough (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional				,			Resolved -)	- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010731498	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Unknown -)		Not reported	ICSR
EU-EC- 10010731636	23/11/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (7d	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
				Economic Area						Recovered/Resolved -), Dyspnoea (7d -	- COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])		

										Myocarditis (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010731674	23/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Axillary pain (n/a - Unknown - Other Medically Important Condition),	n/a - Intramuscular])		
										Chest pain (n/a - Unknown - Other Medically Important Condition),			
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Erythema (n/a - Unknown - Other Medically Important Condition),			
										Feeling cold (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Unknown - Other Medically Important Condition),			
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Mouth injury (n/a - Unknown - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010731771	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Nausea (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010732069	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Influenza (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010732107	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovering/Resolving -), Pyrexia (0d - Recovering/Resolving			
										Vomiting (0d - Recovered/Resolved			
EU-EC- 10010732195	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (29d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Fatigue (29d - Not Recovered/Not Resolved -), Musculoskeletal	n/a])		
EU-EC- 10010732220	23/11/2021	Spontaneous		European	Not	12-17 Years	Adolescent	Male	No	chest pain (29d - Not Recovered/Not Resolved -) Fatigue (1d - Recovering/Resolving	COMIRNATY	Not reported	ICSF
10010/32220			Healthcare Professional	Economic Area	available	Years				-), Hyperhidrosis (1d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010732241	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (9d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
EU-EC- 10010732491	23/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown -),	n/a]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSF

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				Area						Vomiting (n/a - Unknown -)	- COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC- 10010732521	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010732525	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Adhesion (n/a - Unknown -), Headache (n/a - Unknown -), Odynophagia (n/a - Unknown -), Rhinitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010732528	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown -) Adhesion (n/a - Unknown -), Headache (n/a - Unknown -), Odynophagia (n/a - Unknown -), Rhinitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010732530	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010732664	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Chills (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010732868		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No No	Fatigue (1d - Not Recovered/Not Resolved -), Feeling hot (1d - Not Recovered/Not Resolved -), Headache (2d - Not Recovered/Not Resolved -), Influenza (1d - Not Recovered/Not Resolved -), Injection site pain (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Fatigue (5d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
10010732900	23/11/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Addiescent	remare		Recovering/Resolving -), Injection site pain (4d - Not Recovered/Not Resolved -), Lymphadenopathy (2d - Recovered/Resolved -), Myalgia (5d - Not Recovered/Not Resolved -), Nausea (2d - Recovered/Resolved -)		Not reported	ICSR
EU-EC- 10010732983	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010733057		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Headache (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010733090	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Recovered/Resolved -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										(1d - Recovered/Resolved			
EU-EC- 10010733170	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -), Influenza (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Injection site pain (1d - Recovering/Resolving -),			
										Malaise (1d - Recovering/Resolving			
EU-EC- 10010733292	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovering/Resolving -), Malaise (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovering/Resolving			
EU-EC- L0010733326	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
TI EC	22/11/2021	Canadanana	I loolth sous	F	Nat	12.17	Adalasasak	Formula	No	lymphadenopathy (n/a - Unknown -)	.3mL - Intramuscular])	Not reported	TCC
EU-EC- 10010733331	23/11/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
										Myalgia (n/a - Unknown -)	.3mL - Intramuscular])		
EU-EC- 10010733411	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010733425	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	
										Recovering/Resolving -), Pyrexia (2d -	11/4])		
										Recovering/Resolving -)			L
EU-EC- 10010733454	23/11/2021	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	ICS
EU-EC- 10010733503	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- .0010733560	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICS
										Influenza (1d - Recovered/Resolved -),	n/a - [n/a - n/a - n/a])		
										Injection site pain (3d - Recovering/Resolving -),			
										Lymphadenopathy (4d - Not Recovered/Not			
										Resolved -),			

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										Recovered/Resolved			
EU-EC- 10010733737	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (6d - Recovering/Resolving -), Influenza (5d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Recovering/Resolving -), Influenza (6d - Recovering/Resolving			
										-),			
										Injection site pain (3d - Recovering/Resolving -),			
										Pyrexia (6d - Recovering/Resolving -)			
EU-EC- 10010733768	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10010733835	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Headache (0d - Recovered/Resolved -),	n/a])		
										Injection site pain (3d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved			
EU-EC- 10010733912	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010733959	23/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Vaccination site reaction (n/a - Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSF
			Professional							Recovered/Not Resolved -)	- Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010734026	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010734031	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010734106	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010734148	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010734193	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a])	· ICSF
										Chest pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010734278	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	
										Limb discomfort (0d - Recovered/Resolved -),			
										Malaise (0d - Recovered/Resolved			
EU-EC- 10010734283	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010734306	23/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Tachycardia (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

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											n/a - [n/a - n/a - n/a])		
EU-EC- 10010734340	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (13d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICS</u>
:U-EC- .0010734350	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (0d - Not Recovered/Not Resolved -), Nausea (0d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Not Resolved -)	.,, = 1,		
U-EC- 0010734501	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
U-EC- 0010734549	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
										Pyrexia (1d - Recovered/Resolved -)	n/a])		
U-EC- 0010734558	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
										Cough (0d - Recovering/Resolving -),	n/a])		
										Feeling hot (1d - Recovering/Resolving -),			
										Headache (0d - Recovering/Resolving -),			
										Injection site pain (2d - Recovering/Resolving			
EU-EC- 10010734584	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation -	Not reported	ICSI
										Headache (1d - Recovering/Resolving	n/a - [n/a - n/a - n/a])		
										Nausea (0d - Recovered/Resolved -),			
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10010734602	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- L0010734607	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSI
			Professional	Area						-), Injection site pain	- Immunisation - n/a - [n/a - n/a - n/a])		
										(2d - Recovered/Resolved -),			
										Injection site swelling (4d - Recovered/Resolved -)			
EU-EC- 10010734620	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	+ -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Fatigue (n/a - Recovering/Resolving -),	applicable - [n/a - 1{DF} - n/a])		
										Injection site erythema (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not			
										Resolved -), Injection site swelling (n/a - Not			
										Recovered/Not Resolved -), Injection site warmth			

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										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010734663	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (21d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010734688	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovering/Resolving -), Vomiting (0d - Recovered/Resolved			
EU-EC- 10010734904	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010734980	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735099	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Lymphadenopathy (9d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010735155	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735224		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Injection site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735343	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735404	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Feeling hot (8d - Not Recovered/Not Resolved -), Rash (7d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735431	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735466		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Dizziness (1d - Recovered/Resolved -), Influenza (1d - Recovered/Resolved -), Limb discomfort (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735484	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Recovering/Resolving -), Headache (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735504	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Fatigue (1d - Not Recovered/Not Resolved -), Feeling hot (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Injection site pain (1d - Not Recovered/Not Resolved -),			
										Lymphadenopathy (1d - Not Recovered/Not Resolved -)			
EU-EC- 10010735533	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735541	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735590	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735598	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -), Headache (1d - Not Recovered/Not Resolved -), Nausea (2d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735656	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735768	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Injection site pain (7d - Recovered/Resolved -), Nausea (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010735856	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010735945		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Fatigue (1d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Lymphadenopathy (1d - Recovered/Resolved -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736056	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Fatigue (1d - Recovering/Resolving -), Feeling hot (1d - Unknown -), Headache (0d - Unknown -), Influenza (0d - Unknown -), Injection site pain (1d - Unknown -), Limb discomfort (1d - Unknown -), Malaise (1d - Unknown -), Pyrexia (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010736228	23/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (3d - Not Recovered/Not Resolved -), Headache (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736233	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736361	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Recovering/Resolving -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736715	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Feeling hot (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Influenza (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736883	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736894	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Injection site swelling (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736938	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -), Headache (0d - Recovered/Resolved -), Injection site pain (3d - Recovering/Resolving -), Lymphadenopathy (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736946	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Recovered/Resolved -), Influenza (1d - Recovering/Resolving -), Malaise (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736949	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (14d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010736985	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (16d - Recovering/Resolving -), Headache (16d - Recovering/Resolving -), Malaise (16d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010737166	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (7d - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovered/Resolved -)			
EU-EC- 10010737277	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (6d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010737351	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (9d - Recovered/Resolved -), Malaise (5d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (5d - Recovered/Resolved			
EU-EC- 10010737357	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Feeling hot (2d - Recovered/Resolved -),	n/a])		
										Headache (2d - Recovering/Resolving -),			
										Limb discomfort (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10010737428	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Feeling hot (0d - Recovered/Resolved -),	n/a])		
										Headache (6d - Recovering/Resolving -),			
										Injection site pain (2d - Recovered/Resolved -),			
										Malaise (3d - Recovered/Resolved -)			
10010737442	23/11/2021	Spontaneous			Not available	12-17 Years	Adolescent		No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010737583	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Recovered/Resolved -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										(3d - Recovered/Resolved -)			
EU-EC- 10010737590	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved -), Headache (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Recovered/Resolved -), Injection site pain	n/a])		
										(3d - Recovered/Resolved -),			
										Injection site swelling (3d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -)			
EU-EC- 10010737614	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Feeling hot (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -),	n/a])		
										Injection site swelling (1d - Recovered/Resolved			

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										-), Tachycardia (0d - Recovered/Resolved			
EU-EC- 10010737766	23/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Dizziness (0d - Recovered/Resolved -),			
										Influenza (1d - Not Recovered/Not Resolved -)			
EU-EC- 10010737855	23/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Injection site pain (n/a - Recovered/Resolved -),	ii/aj/		
										Injection site swelling (n/a - Recovered/Resolved -)			
EU-EC- 10010706629	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (72h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Fatigue (96h - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (96h - Recovered/Resolved -),			
										Malaise (96h - Recovered/Resolved -),			
										Myalgia (96h - Recovered/Resolved -),			
										Nausea (48h - Recovered/Resolved -),			
										Pyrexia (72h - Recovered/Resolved -),			
										Rash (150h - Recovered/Resolved -)			
EU-EC- 10010706733	22/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010706746	22/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010706749	22/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSF
				Economic Area						Syncope (n/a - Unknown - Other Medically Important Condition),	- COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])		
										Vomiting (n/a - Unknown -)			
EU-EC- 10010706904	22/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010707174	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010707316	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSF
EU-EC- 10010707358	22/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY	Not reported	ICSR

				Area						- Caused/Prolonged Hospitalisation)	- COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 1.0010707417	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Aphasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	IC
										Dysarthria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	indunascalar j)		
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hemiparesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin T increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010707422	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	AVAMYS [FLUTICASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),	<u>IC</u>
										Petechiae (n/a - Not Recovered/Not Resolved - Disabling)	Intramuscular])	MELATONIN [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - Oral]),	
												RELVAR ELLIPTA [FLUTICASONE FUROATE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]),	
												[MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - Oral])	
U-EC- 0010708055	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disturbance in attention (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	[FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]),	<u>IC</u>
										Fatigue (n/a - Unknown -), Headache (n/a - Not	Intramuscular])	[MOMETASONE FUROATE] (C - Nasal congestion - n/a - [n/a - n/a - n/a])	
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
TH FC	22/11/2021	Cnontonoous	Non	Furancan	Not	12.17	Not	Mala	No	Sleep disorder (n/a - Unknown -)	COMIDNIATY	Not reported	Tr
EU-EC- 10010708213	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema nodosum (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>IC</u>
U-EC- .0010708803	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	10
EU-EC- 10010708846	22/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	IC
EU-EC- 10010708910	22/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Child	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	IC
EU-EC- 10010708935	22/11/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10010708978	22/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>IC</u>
EU-EC- 10010709018	22/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[PHENOXYMETHYLPENICILLIN CALCIUM] (C - III-defined disorder - n/a - [n/a - n/a - n/a])	IC
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	applicable - [10]		
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			

										Troponin increased			
										(n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010709105	22/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Conjunctivitis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Lymphocyte count decreased (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	applicable - [n/a - 1{DF} - n/a])		
										Multisystem inflammatory syndrome in children (7d - Recovered/Resolved			
										- Caused/Prolonged Hospitalisation),			
										Petechiae (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pharyngeal enanthema (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (4d - Recovered/Resolved -),			
										Rash maculo-papular (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010709143	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010709151	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Arthralgia (n/a - Not Recovered/Not Resolved -),			
										Chills (n/a - Recovering/Resolving -),			
										Dizziness (7d - Recovered/Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Injection site erythema (n/a - Recovering/Resolving -),			
										Injection site inflammation (n/a - Recovering/Resolving -),			
										Injection site pain (n/a - Recovering/Resolving -),			
										Injection site swelling (n/a - Recovering/Resolving -),			
										Injection site warmth (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			

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											Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving			
											-), Syncope (4d - Recovered/Resolved -),			
											Visual impairment (7d - Recovered/Resolved -),			
											Vomiting (7d - Recovered/Resolved -)			
	EU-EC- .0010709164	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d -	Not reported	ICSR
											Pain (n/a - Recovering/Resolving -),	n/a - Intramuscular])		
											Pyrexia (n/a - Recovering/Resolving -),			
											Vaccination site erythema (n/a - Recovering/Resolving -),			
											Vaccination site oedema (n/a - Recovering/Resolving -),			
											Vaccination site pruritus (n/a - Recovering/Resolving -)			
	:U-EC- .0010709376	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis allergic (2d - Recovered/Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	Not reported	ICSR
												CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])		
	:U-EC- .0010709543	22/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNAT! [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
	:U-EC- .0010709833	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
	EU-EC- .0010710263	22/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Orthostatic hypotension (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			
	:U-EC- .0010710280	22/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Febrile convulsion (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
				 ics/saw dll							Pyrexia (n/a - Recovered/Resolved			60/63

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										- Other Medically Important Condition)				
EU-EC- 10010710337	22/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC- 10010710339	22/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
										Fatigue (n/a - Unknown - Other Medically Important Condition),	11/4 - 11/4])			
										Heart rate (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
										Heart rate increased (n/a - Unknown - Other Medically Important Condition),				
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
										Palpitations (n/a - Unknown - Other Medically Important Condition),				
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
										Pyrexia (n/a - Unknown - Other Medically Important Condition),				
										Tachycardia (n/a - Unknown - Other Medically Important Condition)				
EU-EC- 10010711196	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Dizziness (0d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC- 10010711266	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC- 10010711313	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Petechiae (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
										Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)				
EU-EC- 10010711604	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC- 10010711793	22/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Child	Female	No	Recovered/Not Resolved -) Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR	
				Area						-), Localised oedema (n/a - Recovered/Resolved -),	- n/a - n/a - [1d - n/a - Intramuscular])			
										Lymphadenopathy (n/a - Recovered/Resolved -),				
										Nausea (n/a - Recovered/Resolved -),				
										Neurological symptom (n/a -				

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										Recovered/Resolved -),			
										Paraesthesia (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10010712498	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Injection site haematoma (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Injection site pain (6d - Recovered/Resolved -),	1{DF} - n/a])		
										Syncope (5d - Recovered/Resolved -)			
EU-EC- 10010712506	22/11/2021	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- 10010712623	22/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010712740	22/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anosmia (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
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),	.,, .,,,,,		
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010712769	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
							A.T.			Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			

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