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

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	Child	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- 10010538407	03/11/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Female	No	Blood creatine phosphokinase increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - Oral])	ICSR
										Chest discomfort (n/a - Unknown -),	Intramuscular])		
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Inflammation (n/a - Unknown -),			
										Pain in extremity (n/a - Unknown -), Troponin increased (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	03/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Vaccination site pain (n/a - Unknown -) Chest pain (n/a - Unknown -),	COMIRNATY	Not reported	ICSR
10010538431	03/11/2021	Spontaneous	Professional			Years	Specified	Piale	No	Pericarditis (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSIN
										Troponin increased (n/a - Unknown -)	· · · · ·		
EU-EC- 10010538474	03/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
										Vaccination site pain (n/a - Unknown -),	Intramuscular])		
										Vaccination site reaction (n/a - Unknown -)			
EU-EC- 10010538515	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Initial insomnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[METHOTREXATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [TOCILIZUMAB] (C - n/a - n/a - [n/a - 162mg - n/a])	ICSR
										Tic (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	27	3 / 1/	
EU-EC- 10010539001	03/11/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Life Threatening),	applicable - [1d - n/a - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Headache (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Nausea (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Pain (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Syncope (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Tenderness (n/a - Not Recovered/Not Resolved - Life Threatening)			
EU-EC- 10010539090	03/11/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other	COMIRNATY [TOZINAMERAN]	[OMEPRAZOLE] (C - Gastrooesophageal	ICSR

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			Professional	Economic Area						Medically Important Condition), Dyspepsia (n/a - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	reflux disease - n/a - [n/a - n/a - n/a])	
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important			
EU-EC- 10010539163	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition) Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010539296	03/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Ocular hyperaemia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
				Area						Rash macular (n/a - Recovering/Resolving -),	(S - n/a - n/a - [1d - n/a - Intramuscular])		
										SARS-CoV-2 test negative (n/a	manuscalarjy		
EU-EC- 10010539337	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Recovering/Resolving -) Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010539406	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010539449	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Cerebrovascular accident (n/a - Recovering/Resolving - 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- 10010539562	03/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	[ESCITALOPRAM, ESCITALOPRAM	ICSR
			Professional	Area						Pain in extremity (n/a - Recovered/Resolved -)	(S - n/a - n/a - [n/a - n/a - Intramuscular])	OXALATE] (C - Anxiety, Panic disorder - n/a - [n/a - n/a - n/a]),	
												[MELATONIN] (C - Insomnia - n/a - [n/a - n/a - n/a]),	
												[QUETIAPINE] (C - Anxiety, Panic disorder - n/a - [n/a - n/a - n/a])	
EU-EC- 10010539586	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	- n/a - Intramuscular])		
										Respiratory symptom (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010539644	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Emotional distress (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged			
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2012-02-02-02-02-02-02-02-02-02-02-02-02-02											Hospitalisation),			
DOI-10.0002 DOI-10.0002 Spentamence Description President Doi-10.0002 Do														
### PACCESSION PROFESSION P											Recovering/Resolving - Caused/Prolonged			
BU-5C 1971/2021 Sections No. Baregora Section Sectio														
Bird											Recovering/Resolving - Caused/Prolonged			
Colific (s) - for Extracordinal following Colific (s) - for Extracordinal following Colific (s) - for expected Colific (s) -		03/11/2021	Spontaneous					Adolescent	Female	No	Abdominal pain (n/a - Not		Not reported	ICSR
Secondaria Control Residued 1,				Professional	Area									
BU-EC 0311/2021 Sportlaneous Healthcare European Met 12-17 Addrescrit Plate No.														
Bi-EC 03/11/2021 Sportnessous Healthcase European Not Security														
											Recovered/Not Resolved -),			
EL-FC 03/11/2021 Sportaneous Institute European Not 12-17 Addiscont Mail Not Mail Not Mail Not Mail Not Not Mai											Recovered/Not Resolved -)			
ELFEC 03/11/2021 Spontaneous Histofficare European Not 12-17 Addrescent Male No Ozzates (n/a - secondary (Resched -) Not (TOZIMA/EMVI) Not reported (TOZIMA		03/11/2021	Spontaneous		Economic			Child	Female	No	Resolved - Other Medically	[TOZINAMERAN]	Not reported	ICSR
Professional Economic Professional Economic Professional Economic Professional Economic Professional	ELLEC-	03/11/2021	Spontaneous	Healthcare		Not	12-17	Adolescent	Malo	No		- n/a - n/a])	Not reported	ICSR
EU-EC 03/11/2021 Spontaneous Healthcare European Professional Security Pale Not Professional Security Pal		03/11/2021	Spontaneous		Economic			Adolescent	Male	No	Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19	Not reported	ICSK
EU-EC- 100105410213 Sportaneous Healthcare European Not European European Not European											Recovered/Resolved - Other Medically Important	applicable - [n/a - 1{DF} -		
ELFEC- 10010541038 Professional Economic Area Professional Economic Area Professional Economic Area Profess														
Healthcare Professional Area Professional European		03/11/2021	Spontaneous		Economic			Adolescent	Male	No	thrombosis (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
EU-EC- 10010542021 Spontaneous Healthcare Professional European E		03/11/2021	Spontaneous	Healthcare	Economic			Adolescent	Female	No		[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010542070 O3/11/2021 Spontaneous Non Not reported [COMIRNATY (Care) (Caused/Prolonged Hospitalisation), Pyrexia (24h - Nace) (25h - Nace) (03/11/2021			European Economic				Male	No	Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC- 10010542070 D3/11/2021 Spontaneous Non Healthcare Professional Professional Professional Area Professional Area Professional Professional Area Professional Professional Area Professional					Area						Vaccination failure (n/a - Not Recovered/Not Resolved -	applicable - [1d - n/a - n/a - More in		
Healthcare Professional European Professional European Professional Economic Area Healthcare Professional Economic Area Specified S	FILEC-	03/11/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Condition)	COMIDNATY	Not reported	ICSR
Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation) Pyrexia (24h - Recovered/Resolved - Dylamania (24h - Dylamania (03/11/2021	Sportaneous	Healthcare	European Economic				i idic		Recovered/Not Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not	The reported	1031
EU-EC- 10010542070 EU-EC- 10010542070 EU-EC- 10010542070 Beach Committed Recovered Resolved - Caused (Prolonged Hospitalisation) Not European Economic Area Not European Economic Area Not Every Recovered Resolved -), Coving Recovered Resolved -), Autism spectrum disorder (0d - Recovered/Resolved -), Autism spectrum disorder (0d - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown -), Chillis (n/a - Recovered/Resolved -), Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),											Recovered/Not Resolved - Caused/Prolonged	n/a -		
EU-EC- 10010542070 Spontaneous Healthcare Professional Reconomic Area Professional European Economic Area Professional Professional Economic Area Professional Pr											Pyrexia (24h -			
EU-EC-10010542070 Spontaneous Healthcare Professional European Euro											Caused/Prolonged			
Economic Area Attention deficit hyperactivity disorder (0d - Recovered/Resolved -), Autism spectrum disorder (0d - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown -), Chills (n/a - Recovered/Resolved -), Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),		03/11/2021	Spontaneous						Male	No	Abdominal symptom (0d -		Not reported	ICSR
Autism spectrum disorder (0d - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown -), Chills (n/a - Recovered/Resolved -), Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),					Economic			·			disorder (0d -	immunisation - Not applicable - [n/a -		
Condition), Blood pressure decreased (n/a - Unknown -), Chills (n/a - Recovered/Resolved -), Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),											Autism spectrum disorder (0d - Recovered/Resolved - Other	1,74 1,74])		
Chills (n/a - Recovered/Resolved -), Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),											Condition), Blood pressure decreased (n/a			
Gastroenteritis (0d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),											Chills (n/a -			
Headache (n/a - Recovered/Resolved -),											Gastroenteritis (0d -			
											Headache (n/a -			
											Nausea (n/a -			

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										Respiratory rate increased (0d - Recovered/Resolved -),			
										Stress (0d -			
EU-EC-	03/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Myocarditis (n/a - Unknown -	COMIRNATY	Not reported	ICSR
10010542076	,,		Professional	European Economic Area	available	Years	Specified			Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010542078	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (n/a - Recovered/Resolved - Other Medically Important Condition), Dysphoria (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Skin laceration (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a -			
EII EC	02/11/2021	Spontaneous	Licalthanus	Non	Not	12.17	Not	Male	No	Recovered/Resolved - Other Medically Important Condition)	TOZINAMEDANI	Not reported	ICCD
EU-EC- 10010542316	03/11/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010542367	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Abdominal pain lower (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Cardiac infection (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010542406	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Muscle spasms (12h - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
EU-EC-	02/11/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Cold sweat (n/a - Not	COMIRNATY	Not reported	ICSR
10010542433	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	available	Years	Specified	male	No	Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSK
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown -			
										Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU FC	02/11/2021	Sporton	Non	Non	Not	12 17	Not	Eomale	No	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIDNATY	Not reported	ICCE
EU-EC- 10010542486	U3/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown - Other Medically Important Condition), Tenderness (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Other Medically Important Condition),	n/a - n/a])		
1	l		l 							Vaccination site swelling (n/a -	l	I	

										sung Report			
										Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site warmth (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010543455	03/11/2021	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 -	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010543537	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Feeling abnormal (n/a - Recovered/Resolved -), Hyperhidrosis (n/a -	immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Presyncope (n/a -			
EU-EC- 10010543868	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Amenorrhoea (1mo - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[DROSPIRENONE, ETHINYLESTRADIOL] (C - Contraception - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC- 10010543878	03/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving -),	n/a - n/a]) COMIRNATY [TOZINAMERAN]	[FLUOXETINE, FLUOXETINE	ICSR
			Professional	Area						Nasopharyngitis (n/a - Recovering/Resolving -),	(S - n/a - n/a - [1d - n/a - n/a])	HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral])	
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										SARS-CoV-2 test negative (n/a - Recovering/Resolving -), Vomiting (n/a -			
EU-EC- 10010544038	03/11/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -) Headache (n/a - Recovering/Resolving - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Economic Area						Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-	03/11/2021	Spontaneous		Non	Not	12-17	Not	Not	No	Medically Important Condition) Disease recurrence (n/a -	COMIRNATY	Not reported	ICSR
10010544046			Professional	European Economic Area	available	Years	Specified	Specified		Unknown - Other Medically Important Condition), Nephrotic syndrome (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
EU-EC-	03/11/2021	Spontaneous		Non	Not	12-17		Male	No	Unknown - Other Medically Important Condition) Chest pain (n/a - Not	n/a - n/a]) COMIRNATY	Not reported	ICSR
10010544053			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										Troponin increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010544064	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
				Area						Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - Intramuscular])		
EU-EC-	02/11/2021	Spontaneous	Lloolthoono	Non	Not	12-17	Not	Male	No	Troponin increased (n/a - Recovering/Resolving -) Blood pressure increased (n/a	COMIRNATY	Not reported	ICCD
10010544068	03/11/2021	spontaneous	Professional	European Economic Area	available	Years	Specified	Male	NO	- Recovered/Resolved -), Hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC-	03/11/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Throat tightness (n/a - Recovered/Resolved -) Headache (n/a -	COMIRNATY	Not reported	ICSR
10010544350	55, 11, 2021		Healthcare Professional	Economic	available	Years	Specified			Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19		2010

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										Hiccups (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Myalgia (n/a - Recovering/Resolving -),			
										Nasopharyngitis (n/a - Recovering/Resolving -)			
EU-EC- 10010544469	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
				Alea						Confusional state (n/a - Recovered/Resolved -), Dizziness (n/a -	applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Pain in extremity (n/a -			
										Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other			
EU-EC-	03/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Medically Important Condition) Abdominal pain (n/a -	COMIRNATY	[ISOMETHEPTENE	ICSR
10010544493	03/11/2021	Sportaneous			available	Years	Specified	i iaje		Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19	MUCATE, METAMIZOLE SODIUM, CAFFEINE] (C - n/a - n/a - [n/a -	ICOK
										Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	n/a - n/a])	(C - 1)/a - 1)/a - n/a - n/a])	
										Dizziness (n/a - Recovered/Resolved -),			
										Hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010544579	03/11/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Migraine (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Recovered/Not Resolved -), Weight decreased (n/a - Not	,		
EU-EC-	03/11/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Recovered/Not Resolved -) Lymphadenopathy (n/a - Not	COMIRNATY	Not reported	ICSR
10010544629		·	Professional	Economic Area	available	Years				Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	,	
EU-EC- 10010544678	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Mood altered (n/a - Not Recovered/Not Resolved -),	immunisation - Unknown - [n/a - 1{DF} -		
										Nausea (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10010544681	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Swelling face (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010544689	03/11/2021	Spontaneous	Healthcare	Economic	Not available	12-17 Years	Adolescent	Female	Yes	Malaise (n/a - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area							(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010544719	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypomenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [1d - 1{DF} -		
EU-EC- .0010545045	03/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
U-EC- 0010545063	03/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Not Recovered/Not Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Pyrexia (n/a - Recovering/Resolving -)			
U-EC- 0010545534	03/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	IC
J-EC- 0010545545	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pancreatitis acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICS
U-EC- 0010545567	03/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	IC
U-EC- 0010545572	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
U-EC- 0010545589	03/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
U-EC- 0010546037	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>IC</u>
										Fatigue (36h - Recovered/Resolved -), Headache (36h - Recovered/Resolved -),			
										Malaise (36h - Recovered/Resolved -), Myalgia (36h - Recovered/Resolved -),			
										Nausea (36h - Recovered/Resolved -), Pyrexia (36h -			
:U-EC- 0010546389	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Arthralgia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Dizziness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Ear swelling (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Headache (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash pruritic (0d - Recovered/Resolved - Caused/Prolonged			

	1.50									Vaccination site pain (12d - Recovered/Resolved With Seguelae - Caused/Prolonged			
EU-EC- 10010546574	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Cold sweat (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Heart rate decreased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 in munisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Unknown -), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Tinnitus (n/a - Recovered/Resolved -), Vertigo (n/a -			
EU-EC- 10010546576	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Appendicitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010546810	03/11/2021	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 -	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10010547225	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (77d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (77d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (77d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Tachycardia (77d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (19d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010547354	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Menstrual disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
	03/11/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovering/Resolving -) COVID-19 (n/a - Unknown -	n/a]) COMIRNATY	Not reported	ICSR
10010547445			Professional	Economic Area	available	Years				Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
	03/11/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Important Condition) Cough (n/a -	COMIRNATY	Not reported	ICSR
10010547467			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010547482	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (25d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010548083	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010548156	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	AVAMYS [FLUTICASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - n/a]),	ICSR

										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Folliculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lip erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lip oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lip oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lip pain (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mucosal infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oral discomfort (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pharyngeal erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pharyngeal erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pharyngeal erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pharyngitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ISOTRETINOIN] (C - Acne - n/a - [403d - 20mg - Oral])	
THE FO	02/11/2021	Constant	l lashbasas		Net	12.17	Adolescent	Mala	No	Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIDMATY	Network	Tech
EU-EC- 10010548205	03/11/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diplopia (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Eyelid ptosis (n/a - Unknown - Caused/Prolonged Hospitalisation), IIIrd nerve paresis (31d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010548543	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Asthenia (1d - Recovered/Resolved - Other Medically Important Condition), Back pain (1d - Recovered/Resolved - Other Medically Important Condition), Balance disorder (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

							_						
										Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Feeling cold (n/a - Unknown - Other Medically Important Condition),			
										Feeling jittery (n/a - Unknown - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010548777	03/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
100103 10///			Professional		available	rears				Circulatory collapse (n/a - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Rash (0d - Recovering/Resolving -),			
										Rash (n/a - Not Recovered/Not			
										Resolved -), Urticaria (n/a - Not			
EU-EC-	03/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Recovered/Not Resolved -) Abdominal pain (4d -	COMIRNATY	Not reported	ICSR
10010548841	05/11/2021	эропшисоцэ	Healthcare Professional	Economic Area	available	Years	Adolescent	Maic		Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation	Not reported	ICSIC
										Headache (8d - Not Recovered/Not Resolved -),	- n/a - [n/a - n/a - n/a])		
										Nausea (4d - Recovering/Resolving -)			
EU-EC- 10010507970	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area			ľ			Pericardial effusion (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
										Pericarditis (n/a - Not Recovered/Not Resolved -)	indumascalar j)		
EU-EC- 10010508146	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010508148	02/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Economic Area						Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010508219	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Feeling cold (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Lymph node pain (n/a - Recovering/Resolving -),	(S - COVID-19 immunisation - Not applicable - [1d -		
										Malaise (n/a	n/a - Intramuscular])		
EU-EC- 10010508486	02/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -) Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010300400			Professional	Economic Area	avaijabje	lears	эрестеи			Myalgia (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a -		
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10010508519	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Pyrexia (n/a - Unknown -),			
					Not	12-17			No	Troponin increased (n/a - Unknown -)			
EU-EC-		Spontaneous		Non			Not	Male		Myocarditis (n/a -	COMIRNATY	Not reported	ICSR

7.11.2022		l	I	l	l			Kair E			applicable - [n/a -		ı
EU-EC- 10010509124	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
EU-EC- 10010509277	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Asthenia (n/a - Unknown -), Asthma (n/a - Unknown -), COVID-19 (n/a - Unknown -	n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSI
										Other Medically Important Condition), Cough (n/a - Unknown -),	n/a - n/a])		
										Illness (n/a - Unknown -), Nasal congestion (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -), Vaccination failure (n/a - Unknown - Other Medically			
EU-EC- 10010509665	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Dermatitis allergic (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010509732	02/11/2021	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 -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Unknown - Other Medically Important Condition)	-		
EU-EC- 10010509865	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal withdrawal bleeding (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC-	02/11/2021	Coontangous	Non	Europoan	Not	12-17	Not	Female	No	Not Recovered/Not Resolved -	1{DF} - n/a]) COMIRNATY	Not reported	ICCI
10010509894	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	available	Years	Specified	remale	INO	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICS</u>
										Headache (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -			
), Myalgia (n/a - Recovering/Resolving -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a -			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Recovering/Resolving -) Headache (n/a - Not	COMIRNATY	Not reported	ICSR
10010509905		·	Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	·	
										Pyrexia (n/a - Recovering/Resolving -),	1{DF} - n/a])		
										Vomiting (0d - Recovered/Resolved -)			
EU-EC- 10010509943	02/11/2021	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 - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010510187	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
				Area						Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010510233	02/11/2021	Spontaneous		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 -	Not reported	ICSF
EU-EC- 10010510255	02/11/2021	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)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
									<u> </u>	<u> </u>	n/a - n/a])		

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EU-EC- 10010510268	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010510318	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving - Other Medically Important Condition) Dyspnoea (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Disabling, Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Disabling, Other Medically Important Condition), Varicella (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition) Varicella (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010510335	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	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 Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010510348	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition), Hypoacusis (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition), Presyncope (1d - Recovered/Resolved - Other Medically Important Condition), Presyncope (1d - Recovered/Resolved - Other Medically Important Condition), Vision blurred (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- 10010510350	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (3d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010510360	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Ma l e	No	Medically Important Condition) Dysgeusia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
			Professional	Area							(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010510382	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010510461	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Back pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d	Not reported	ICS
										Chest pain (n/a - Recovered/Resolved -), Flank pain (n/a -	- n/a - n/a])		
										Recovered/Resolved -), Neck pain (n/a -			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved -) Fatigue (n/a - Not	COMIRNATY	Not reported	ICS
10010510503	02/11/2021	эропшисоиз	Healthcare	Economic Area	available	Years	Specified	Temale	NO	Recovered/Not Resolved -), Headache (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	1031
										Recovered/Not Resolved -), Injection site pain (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved -), Malaise (n/a - Not			
										Recovered/Not Resolved -), Nausea (n/a - Not			
										Recovered/Not Resolved -), Pyrexia (n/a - Not			
										Recovered/Not Resolved -), Vomiting (n/a - Not			
	02/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Not Resolved -) Menstruation delayed (n/a -	COMIRNATY	Not reported	ICSF
10010510507			Healthcare Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010510511	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSI
										Injection site pain (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010510521	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Headache (1d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
<u></u>	00/11/2001			_		10.17				Injection site pain (n/a - Not Recovered/Not Resolved -)	CONTRACTO		1000
EU-EC- 10010510884	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Cyanosis (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - Disabling),	[[i/a - i/a - i/a])		
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			
										Feeling cold (n/a - Not Recovered/Not Resolved - Disabling),			
										Heart rate decreased (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Disabling),			
										Respiratory symptom (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10010510899	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Eyelid oedema (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a -	Not reported	ICSF
										Fatigue (n/a - Recovering/Resolving -),	[n/a - n/a - n/a])		
										Hypoaesthesia (n/a - Recovering/Resolving -),			
										Lip oedema (n/a -			

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										Oral disorder (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -),			
										Pain in extremity (n/a -			
										Recovering/Resolving -), Pyrexia (n/a -			
EU-EC-	02/11/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovering/Resolving -) Gastroenteritis (n/a -	COMIRNATY	Not reported	ICSR
10010510943			Professional	Economic Area	available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])		
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010511133	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depersonalisation/derealisation disorder (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
										Dissociation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	, , , , , , , , , , , , , , , , , , ,		
EU-EC- 10010511154	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
EU-EC- 10010511190	02/11/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not	Male	No	Syncope (n/a - Recovered/Resolved - Other	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010311190			Professional	European Economic Area	available	rears	Specified			Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010511214	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
EU-EC-	02/11/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Menstruation delayed (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10010511253			Professional	Economic Area	available	Years				Recovered/Resolved -), Tremor (n/a -	[TOZINAMERAN] (S - n/a - n/a - [1d - n/a -		
EU-EC-	02/11/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Myocarditis (n/a - Not	Intramuscular]) COMIRNATY	Not reported	ICSR
10010511349			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	·	
EU-EC- 10010511351	02/11/2021	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)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
EU-EC- 10010511354	02/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Economic Area						Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010511357	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness postural (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Malo	No	Urticaria (1d - Recovered/Resolved - Other Medically Important Condition) Circulatory collapse (0d -	COMIRNATY	Not reported	ICSR
10010511501	02/11/2021	Spontaneous	Healthcare Professional	Economic	available	Years	AUDICOCCIIL	male	INO	Recovered/Resolved - Other Medically Important Condition), Malaise (0d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	oc reported	ICSK
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Influenza (1d -	COMIRNATY	Not reported	ICSR
10010511559		,	Healthcare Professional	Economic	available	Years				Recovering/Resolving -), Musculoskeletal chest pain (1d - Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	,	
										Pyrexia (1d -			
										Recovering/Resolving -),			

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EU-EC- 10010511838	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diplopia (0d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -), Hyperventilation (0d - Recovered/Resolved -), Tachycardia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010512083	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (0d - Recovered/Resolved -)			
EU-EC- 10010512264	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1min - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010512325	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovering/Resolving -), Fatigue (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Presyncope (0d - Recovering/Resolving -)			
EU-EC- 10010512413	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (8d - Recovering/Resolving -), Rash (8d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010512890	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (12d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010513233	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010513317	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Bradycardia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (1d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Limb discomfort (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Paraesthesia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Unresponsive to stimuli (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010513407	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Balance disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vestibular neuronitis (n/a - Recovering/Resolving -			

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										Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010513461	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (7d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Limb discomfort (7d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Somnolence (7d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010513562	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haematoma (0d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
			Professional	Alea						Headache (0d - Recovering/Resolving -),	- n/a - [n/a - n/a - n/a])		
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Rash (0d - Unknown -) Chest discomfort (16d - Not	COMIRNATY	Not reported	ICSR
10010513748	,,		Healthcare Professional	Economic	available	Years				Recovered/Not Resolved -), Cough (16d - Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -		
										Recovered/Not Resolved -),	n/a])		
										Fatigue (16d - Not Recovered/Not Resolved -),			
										Gastrointestinal pain (16d - Not Recovered/Not Resolved -),			
										Headache (16d - Not Recovered/Not Resolved -),			
										Hypotonia (16d - Not Recovered/Not Resolved -),			
										Influenza (16d - Not Recovered/Not Resolved -),			
										Limb discomfort (16d - Not Recovered/Not Resolved -),			
										Lymphadenopathy (16d - Not Recovered/Not Resolved -),			
										Nausea (16d - Not Recovered/Not Resolved -)			
EU-EC- 10010514122	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Syncope (0d - Recovering/Resolving - Caused/Prolonged	n/a])		
EU-EC- 10010514511	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Dizziness (24d - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Caused/Prolonged Hospitalisation), Fatique (24d - Not	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (24d - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010514536	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Headache (1d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Hospitalisation), Movement disorder (1d -	- n/a - [n/a - n/a - Subcutaneous])		
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010514556	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Juvenile idiopathic arthritis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Multiple sclerosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Optic neuritis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010514578	02/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Tachycardia (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	n/a])		
EU-EC- 10010514648	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (2d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dizziness postural (2d - Recovered/Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Insomnia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (4d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010514669	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),	11/a - 11/a <u>]</u>)		
										Troponin increased (n/a - Recovering/Resolving -)			
EU-EC- 10010514742	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (109d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (109d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	1,4])		
										Fatigue (109d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Palpitations (109d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Tachycardia (109d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010514834	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (4d - Recovered/Resolved -), Headache (3d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Recovered/Resolved -), Malaise (3d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (1d - Recovered/Resolved -)			
EU-EC- 10010514838	02/11/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -),	[TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Headache (2d - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Injection site erythema (4d - Recovered/Resolved -),			
										Injection site haematoma (4d - Recovered/Resolved -),			
										Injection site inflammation (4d - Recovered/Resolved -),			
										Injection site pain (4d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			

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										Myalgia (3d - Recovered/Resolved -),			
										Polymenorrhoea (n/a - Recovering/Resolving -)			
EU-EC- 10010514870	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010514877	02/11/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010514908	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010514911	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (n/a - Recovered/Resolved -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010514967	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oral allergy syndrome (78d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10010515090	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Interchange of vaccine products (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]), SPIKEVAX [COVID- 19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID-19	Not reported	ICSF
EU-EC- 10010515240	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [n/a - 1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010515344	02/11/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010515351	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), Tramps (n/a)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Tremor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010515410	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diabetic ketoacidosis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010515454	02/11/2021	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 -	Not reported	ICSF
EU-EC- 10010515455	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysphonia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypersensitivity (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010515464	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR

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EU-EC- 10010515608	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphangitis (n/a - Recovering/Resolving - Caused/Prolonged	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010515655	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Genital herpes (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010515666	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diplopia (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010515681	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea exertional (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Myocarditis (10d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (10d - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Tachycardia (9d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010515703	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (9d - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (9d - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010515781	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Dyspnoea (4h - Recovered/Resolved - Disabling), Dyspnoea (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010515791	02/11/2021	Spontaneous	Non Healthcare Professional		Not available		Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dizziness (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), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Somnolence (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- 10010515821		Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent		No	Fatigue (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010516283	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Monoplegia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010516533	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICS
EU-EC- 10010516638	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (1d - Recovered/Resolved -) Orchitis (n/a - Not Recovered/Not Resolved -)	- n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	IC
:U-EC- 0010516693	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Chest pain (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	liva])		
										Ventricular extrasystoles (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
:U-EC- .0010516991	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Malaise (0d - Recovered/Resolved -)			
EU-EC- 10010517248	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>IC</u>
										Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010518196	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovered/Resolved -), Rash (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>IC</u>
EU-EC- 10010518359	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Erythema (2d - Recovered/Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	IC
			FTOTESSIONAL	Alea						Fatigue (2d - Recovered/Resolved -), Headache (2d -	- n/a - [n/a - n/a - n/a])		
										Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -),			
										Pyrexia (2d -			
EU-EC- 10010518417	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICS
										Injection site pain (1d - Recovered/Resolved -), Lymphadenopathy (2d -	- n/a - [n/a - n/a - n/a])		
										Unknown -),			
EU-EC- 10010518465	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Ma l e	No	Pyrexia (1d - Unknown -) Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
				Alea						Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010518479	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS

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										Vaccination failure (n/a - Unknown - Other Medically	applicable - [1d - n/a - n/a])		
EU-EC- 10010518499	02/11/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Blood pressure increased (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Nausea (0d - Recovered/Resolved -),			
EU-EC-	02/11/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Presyncope (n/a - Recovered/Resolved -) Chest pain (2d -	COMIRNATY	Not reported	ICSF
10010518504			Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Lymph node pain (n/a - Unknown - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Unknown - Other Medically Important Condition),			
										Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010518523	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010519116	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (8d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
			Professional	Area						Rash (8d - Recovering/Resolving -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010519120	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Influenza (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Recovering/Resolving -), Limb discomfort (3d -	n/a])		
										Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10010519477	02/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			Torcasional	Aica						Menstrual disorder (n/a - Unknown -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Oligomenorrhoea (n/a - Unknown -)			
EU-EC- 10010519489	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a -	ICSR
										Menstrual discomfort (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - n/a])	
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010519845	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10010519875	02/11/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Economic Area						Medically Important Condition), Neck pain (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
ELLEC	02/11/2021	Cnontara	Hoolth as	Non	Net	12.17	Not	Mala	No	Recovering/Resolving - Other Medically Important Condition)	COMIDMATY	Not reported	ICCE
EU-EC-	02/11/2021	Spontaneous	nealthcare	Non	Not	12-17	Not	Male	No	Lethargy (n/a - Not	COMIRNATY	Not reported	ICSR

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10010519898			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Not Recovered/Not Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010519938	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blindness unilateral (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Deafness unilateral (15d - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Hospitalisation), Facial paralysis (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myalgia (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Paraesthesia (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Thrombosis (15d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010520023	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (0d - Recovered/Resolved -), Injection site pain (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010520172	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Rash (52d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	n/a])		
EU-EC- 10010520267	02/11/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Musculoskeletal chest pain (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Palpitations (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vertigo (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010520603	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010520610	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010520613	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Medically Important Condition) Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	rya - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010520615	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved -	n/a - n/a])		

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										Other Medically Important Condition),			
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010520831	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (3d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	Drug withdrawn - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010520853	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010520952	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram T wave inversion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Epistaxis (n/a - Not Recovered/Not Resolved -),	n/a - n/a])		
										Haematemesis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pulmonary embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rectal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling (n/a - Not Recovered/Not Resolved -),			
										Tachycardia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010520964	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Blood pressure decreased (15min - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Bradycardia (n/a - Unknown - Other Medically Important Condition),			
										Cyanosis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (15min - Recovered/Resolved - Other Medically Important Condition),			
										Hyperhidrosis (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)			
EU-EC- 10010521021	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010521024	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Unknown -),	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Headache (n/a - Unknown -), Vertigo (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
EU-EC- 10010521051	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											1{DF} - Intramuscular])		
EU-EC- 10010521056	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010521115	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010521401	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010521412	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Nausea (1d - Recovered/Resolved -), Urticaria (n/a - Recovering/Resolving -), Vomiting (1d -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010521432	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Skin exfoliation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010521745	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (47d - Recovering/Resolving -), Headache (47d - Recovering/Resolving -), Vomiting (47d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010521750	02/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (47d - Recovering/Resolving -), Headache (47d - Recovering/Resolving -), Vomiting (47d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010522332	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) Dizziness (5d - Recovered/Resolved -), Headache (4d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Pyrexia (4d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010522591	02/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Dizziness (1d - Recovered/Resolved -), Fatigue (1d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010522736	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010522744	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010523161	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010523162	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10010523317	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (n/a - Unknown -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Myalgia (1d -	Intramuscular]) COMIRNATY	Not reported	ICSR

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1001	0523355			Healthcare Professional		available	Years	Specified			Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-E0	C- .0523483	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Asthenia (2d - Not Recovered/Not Resolved -),		Not reported	<u>ICSR</u>
1001	.0323463			Professional		available	rears				Back pain (2d - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
											Headache (2d - Not Recovered/Not Resolved -),	11, 41,		
											Myalgia (2d - Not Recovered/Not Resolved -),			
											Somnolence (2d - Not Recovered/Not Resolved -)			
EU-E6 1001	C- 0523810	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		ATOMOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]),	ICSR
											Attention deficit hyperactivity disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[RISPERIDONE] (C - n/a - n/a - [n/a - n/a - Oral])	
											Blepharospasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Eyelid myoclonus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Gaze palsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-E0	C- .0523871	02/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
1001	.55250/1			. Toressional	Economic Area	available	icuis	Specificu			Feeling cold (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a -		
											Headache (n/a - Not Recovered/Not Resolved -),	.3mL - Intramuscular])		
											Malaise (n/a - Not Recovered/Not Resolved -),			
											Musculoskeletal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Osteomyelitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged			

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										Hospitalisation, Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Sacroiliitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010523888	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Multisystem inflammatory syndrome in children (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010523978	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (3d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved - Disabling),	applicable - [0d - .3mL - Intramuscular])		
										Somnolence (1d - Recovered/Resolved - Disabling),			
										Vaccination site pain (4d - Recovered/Resolved - Disabling)			
EU-EC- 10010524294	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asphyxia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	Unknown - [n/a - .3mL - Intramuscular])		
										Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010524301	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Drug ineffective (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010524444	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Palpitations (n/a - Recovering/Resolving -),	n/a])		
										Panic attack (n/a - Recovering/Resolving -), Tachycardia (n/a -			
EU-EC- 10010525430	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Recovering/Resolving -) Nasopharyngitis (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Paranasal sinus hyposecretion (1d - Recovering/Resolving -),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU EO	00/11/0001			_		10.15				Throat irritation (1d - Recovering/Resolving -)	CONTRACTO		7000
EU-EC- 10010525557	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cyanosis (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			

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										Paraesthesia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not			
EU-EC-	02/11/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Recovered/Not Resolved -) Feeling cold (n/a -	COMIRNATY	Not reported	ICSR
10010525717			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Headache (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not		
										Recovered/Resolved -), Lethargy (n/a -	applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Pallor (n/a -			
										Recovered/Resolved -), Syncope (n/a -			
EU-EC-	02/11/2021	Spontaneous	Non	Europoan	Not	12-17	Adolescent	Eomalo	No	Recovered/Resolved - Other Medically Important Condition) Fatique (1d -	COMIRNATY	Not reported	ICSR
10010525911	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	available	Years	Adolescent	remale	INO	Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation	Not reported	<u>ICSK</u>
										Headache (1d - Recovering/Resolving -),	- n/a - [n/a - n/a - n/a])		
										Paraesthesia (1d - Recovering/Resolving -),			
										Vaccination site pain (1d - Recovering/Resolving -)			
EU-EC- 10010525917	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
			Professional	Alea						Fatigue (1d - Recovered/Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (1d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10010526381	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Lip injury (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			, , , , , , , , , , , , , , , , , , , ,	Area		100.0	Speemaa			Syncope (1min - Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010526434	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Dizziness (n/a - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010526463	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
											- n/a - [n/a - n/a - n/a])		
EU-EC- 10010526787	02/11/2021	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 -	Not reported	ICSR
EU-EC-	02/11/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Rash (n/a - Not Recovered/Not		Not reported	ICSR
10010526907			Healthcare Professional	Economic Area	available	Years				Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010526970	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Influenza (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area							(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010527012	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area							(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010527018	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Fatigue (2d - Recovering/Resolving -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Feeling hot (2d - Recovering/Resolving -),			
										Headache (2d - Recovering/Resolving -),			
										Limb discomfort (1d - Recovered/Resolved -),			
										Pyrexia (2d - Recovering/Resolving -),			
										Vomiting (1d -			
										Recovered/Resolved -)			

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EU-EC- 10010527475	02/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -), Injection site swelling (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
EU-EC-	02/11/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Dizziness (2d -	n/a]) COMIRNATY	Not reported	ICSF
10010527628			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (1d - Recovered/Resolved -),	.,,-1)		
										Injection site pain (6d - Recovered/Resolved -),			
										Injection site swelling (4d - Recovered/Resolved -),			
										Limb discomfort (1d - Recovered/Resolved -)			
EU-EC- 10010527746	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -),	- n/a - [n/a - n/a - n/a])		
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10010528052	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -),	[TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),	- n/a - [n/a - n/a - n/a])		
										Headache (1d - Recovered/Resolved -),			
										Influenza (1d - Recovered/Resolved -),			
										Malaise (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -), Vomiting (1d -			
EU 50	02/11/2021			_		12.17			ļ.,	Recovered/Resolved -)	CONTRACTO		1000
EU-EC- 10010528299	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
	00/44/2004					12.17			ļ.,	Recovered/Resolved -)	n/a])		1000
EU-EC- 10010528463	02/11/2021	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Troponin increased (n/a - Recovering/Resolving -)	applicable - [n/a - n/a - n/a])		
EU-EC- 10010528490	02/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSF</u>
10010528490			Professional	Economic Area	avallable	rears	Specified			Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010528501	02/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Hypophagia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Nausea (n/a - Unknown -), Pallor (n/a - Unknown -),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Syncope (n/a - Unknown -	.,,,		
										Other Medically Important Condition)			
EU-EC- 10010528568	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Fatique (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Recovered/Resolved -), Limb discomfort (1d -	n/a])		
										Recovered/Resolved -), Pyrexia (1d -			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Injection site erythema (2d -	COMIRNATY	Not reported	ICSR
10010528606	02/11/2021	Spontaneous	Healthcare Professional	Economic Area	available	Years	Adolescent	inale	NO	Recovering/Resolving -), Myalqia (1d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSN
EU-EC-	02/11/2021	Sportanceura	Non	Furencen	Not	12-17	Adolescent	Malo	No	Recovering/Resolving -)	n/a])	Not reported	TOOP
10010528722	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Audiescent	i*iale	No	Injection site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010528810	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -),	n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSF
			Professional	Area						Injection site pain (2d - Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010528950	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						,	(S - Immunisation		

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EU-EC-	02/11/2021	Chontanoous	Non	Europoan	Not	12-17	Adolescent	Eomalo	No	Dizziness (1d -	n/a]) COMIRNATY	Not reported	ICSR
10010529107	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Adolescent	remale	INO	Recovered/Resolved -), Fatigue (1d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Recovered/Resolved -), Headache (1d -	n/a])		
EU-EC- 10010529128	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Not Specified	No	Recovered/Resolved -) Fatigue (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10010323120			Professional	Area	available	100.3		Эрсста		Injection site swelling (1d - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Myalgia (1d - Not Recovered/Not Resolved -),			
										Paraesthesia (0d - Recovered/Resolved -)			
EU-EC- 10010529236	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010529254	02/11/2021	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 - n/a])	Not reported	ICSR
EU-EC- 10010529275	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]	Not reported	ICSR
EU-EC- 10010529846	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -), Injection site swelling (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Recovered/Resolved -) Fatigue (6d -	n/a]) COMIRNATY	Not reported	ICSR
10010530270	02/11/2021	Spontaneous	Healthcare Professional	Economic Area	available	Years	Adolescent	remale	INO	Recovering/Resolving -), Headache (6d - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
										Vomiting (0d - Not	ii/aj/		
EU-EC- 10010530275	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved -) Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Headache (0d - Recovered/Resolved -), Injection site pain (1d -	- n/a - [n/a - n/a - n/a])		
EU-EC-		Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Headache (n/a - Not	COMIRNATY	Not reported	ICSR
10010530366			Healthcare Professional		available	Years				Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010530390	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (0d - Recovering/Resolving -), Dyspnoea (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010530395	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) Abnormal faeces (0d - Recovered/Resolved -)	n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010330393			Professional	Area	available	rears				Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])		
EU-EC- 10010530644	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area						Headache (0d - Recovered/Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Injection site erythema (2d - Recovered/Resolved -)			
EU-EC- 10010531182	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010531260	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
	+	+	+	+	+	+	+	+	-	+	-(-, 1/4] <i>)</i>	+	$\overline{}$

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EU-EC- 10010531344	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010531358	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010531433	02/11/2021	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- 10010531645	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -), Lymphadenopathy (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010531868	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Cough (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010531874	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (1d - Recovering/Resolving -), Dizziness (1d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Influenza (3d - Recovering/Resolving -), Lymphadenopathy (1d - Recovering/Resolving -), Nausea (0d - Recovered/Resolved -), Vaccination site reaction (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010531995	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) 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- 10010532044	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010532078	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Rash pruritic (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010532282	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010532392	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Influenza (n/a - Recovered/Resolved -), Injection site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010532400	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Fatigue (1d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (1d - Recovering/Resolving -), Malaise (1d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010532404	02/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (13d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010532543	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blindness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Recovered/Not Resolved - Other Medically Important Condition),	Unknown])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Migraine with aura (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Photophobia (n/a - Not			
										Recovered/Not Resolved -), Photopsia (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -) Headache (n/a -	COMIRNATY	Not reported	ICSR
10010532560	02,11,2021		Healthcare Professional	Economic Area	available	Years	7.44313333116			Recovered/Resolved -), Malaise (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not	l l l l l l l l l l l l l l l l l l l	2001
										Recovered/Resolved -), Menstruation delayed (n/a -	applicable - [n/a - 1{DF} - n/a])		
										Not Recovered/Not Resolved -			
										Myalgia (n/a - Recovered/Resolved -),			
	22/11/2021									Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10010532839	02/11/2021	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 - n/a])	Not reported	ICSR
EU-EC- 10010532950	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Headache (0d - Recovered/Resolved -),	- n/a - [n/a - n/a - n/a])		
										Injection site pain (2d - Recovered/Resolved -),			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Pyrexia (0d - Recovered/Resolved -) Chills (0d -	COMIRNATY	Not reported	ICSR
10010533082			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Headache (0d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	,	
										Recovered/Resolved -), Injection site pain (2d -	n/a])		
EU-EC- 10010533316	02/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Erythema (n/a - Recovering/Resolving - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010333310			rioressional	Area	available	rears				Medically Important Condition),	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} -		
										Microscopic polyangiitis (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a])		
										Tenderness (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010533402	02/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010533687	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovering/Resolving -),	n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area		. 50/3				Injection site swelling (2d - Recovering/Resolving -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010533739	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
			Totessional	A Ca						Injection site pain (1d - Not Recovered/Not Resolved -),	- n/a - [n/a - n/a - n/a])		
										Vaccination site reaction (1d - Not Recovered/Not Resolved -)			
EU-EC- 10010533860	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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			Professional	Area							(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010534071	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (28d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10010534188	02/11/2021	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	IC
										Fatigue (2d - Recovered/Resolved -),	- n/a - [n/a - n/a - n/a])		
										Headache (2d - Recovered/Resolved -),			
										Injection site pain (2d - Recovered/Resolved -),			
										Limb discomfort (2d - Recovered/Resolved -)			
EU-EC- 10010534212	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	IC
	02/11/2021	Cot	Non	F	Net	12.17	A d a l a a a a a b	FI-	No	Fatigue (1d - Recovered/Resolved -)	- n/a - [n/a - n/a - n/a])	Ni-t	IC
EU-EC- 10010534263	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	<u>IC</u>
										Headache (2d - Recovering/Resolving -),	- n/a - [n/a - n/a - n/a])		
										Injection site pain (2d - Recovered/Resolved -),			
										Limb discomfort (0d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10010534323	02/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Feeling hot (0d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>IC</u>
			Professional	Area						Influenza (0d - Not Recovered/Not Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010534409	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10010534469	02/11/2021	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 - n/a])	Not reported	ICS
EU-EC- 10010534507	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovered/Resolved -), Nausea (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	IC
EU-EC-	02/11/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Pericardial effusion (n/a - Not	n/a]) COMIRNATY	Not reported	IC:
10010534510			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Recovered/Not Resolved - Other Medically Important Condition)	, , ,		
EU-EC- 10010535342	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (13d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
EU-EC- 10010535436	02/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Injection site swelling (1d - Recovered/Resolved -)	n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010333130			Professional		uvaliable	rears				necovered/nesoved /	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010535635	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (9d - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	IC
										Blood pressure increased (11d - Recovered/Resolved -),	- n/a - [n/a - n/a - n/a])		
										Fatigue (13d - Unknown -),			
EU EC	02/11/2021	Caratana		F	Net	12.17	A d = 1 = = = = +	NA-I-	Na	Pyrexia (7d - Unknown -)	COMIDNIATY	Nat	100
EU-EC- 10010535956	02/11/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Arrhythmia (n/a - Fatal - Results in Death), Cardiac failure acute (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICS
										Fatal - Results in Death),	- [n/a - 1{DF} - Intramuscular])		
										Hypoventilation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -),			
										Pulmonary oedema (n/a - Fatal - Results in Death)			
EU-EC-	01/11/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Facial paralysis (n/a - Not	COMIRNATY	Not reported	ICS

10010499839			Professional	Economic Area		Years				Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10010500613	01/11/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICS</u>
			Professional	Area						Headache (n/a - Recovered/Resolved -),	(S - n/a - n/a - [1d - n/a - Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved -),			
										Rhinitis (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010501081	01/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19	Not reported	<u>ICS</u>
										Fatigue (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010501098	01/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a -	Not reported	<u>ICSF</u>
U-EC- .0010501303	01/11/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Abdominal pain (n/a - Not Recovered/Not Resolved -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSI
				Area		, suit	opeo.mea			Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Hypomenorrhoea (n/a - Unknown -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -),			
EU-EC-	01/11/2021	Caantanaaya	Non	Fureneen	Not	12-17	Adolescent	Mala	No	Premenstrual pain (n/a - Unknown -) Headache (3d -	COMIRNATY	Not reported	TCCI
10010501765	01/11/2021	Spontaneous	Healthcare		Not available	Years	Adolescent	Male	INO	Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Puncture site oedema (3d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- .0010501870	01/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	<u>ICSI</u>
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	- n/a - [n/a - n/a - Intramuscular])		
										Lymph node pain (n/a - Not Recovered/Not Resolved -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010501884	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C	ICSI
			Troressional	Area						Fall (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])	- Depression - n/a - [n/a - n/a - n/a])	
										Pain in extremity (1d - Unknown - Other Medically Important Condition),			
										Presyncope (1d - Recovered/Resolved - Other Medically Important Condition),			
										Tinnitus (n/a - Unknown - Other Medically Important Condition),			
										Tremor (n/a - Recovered/Resolved - Other Medically Important			

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										Visual impairment (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010501915	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Disabling, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Disabling, Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Psychiatric symptom (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Weight decreased (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10010502041	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010502047	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Chest pain (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010502061	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (5d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10010502213	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (1d - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Seizure (1d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010502274	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010502532	01/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Amnesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			

											g			
											Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Febrile convulsion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Nystagmus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Rhinitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											SARS-CoV-2 test negative (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Suffocation feeling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
	EU-EC- 10010502545	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
											Tinnitus (n/a - Unknown - Other Medically Important Condition)	n/a - n/a])		
	EU-EC- 10010502555	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry eye (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[PARACETAMOL, PARACETAMOL PH. EUR.] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
											Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a - n/a])	1,01)	
											Oral herpes (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition),			
											Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
- 1											,,			
											Pyrexia (n/a - Unknown - Other Medically Important Condition),			
											Pyrexia (n/a - Unknown - Other Medically Important			
											Pyrexia (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically			
											Pyrexia (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tonsillitis (n/a - Unknown - Other Medically Important			
	EU-EC- 10010502571	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tonsillitis (n/a - Unknown - Other Medically Important Condition), Viral pharyngitis (n/a - Recovering/Resolving - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

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										Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Shock (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010502890	01/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a	ICSR
										Menstrual disorder (n/a - Unknown -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010503998	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pancreatitis acute (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10010504000	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Abdominal pain lower (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Bedridden (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Periorbital swelling (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010504025	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cervical radiculopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Immobilisation syndrome (n/a			

										- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neuralgic amyotrophy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Presyncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010504133	01/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Caused/Prolonged Hospitalisation), Swelling face (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
											immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010505043		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Headache (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Syncope (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 is munisation - Not applicable - [n/a - 1{DF} - n/a])	[FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010505276	01/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nasal congestion (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
EU-EC- 10010505544	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Discomfort (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza (n/a - Unknown - Other Medically Important Condition), Migraine (n/a - Unknown - Other Medically Important Condition),	n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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											Condition), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other			
											Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
											Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10010505558	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Cyanosis (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN]	[ETHINYLESTRADIOL, NORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
											Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a - n/a])		
											Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Livedo reticularis (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
	EU-EC- 10010505784	01/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area			Not Specified	Male	No	COVID-19 (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 - Unknown - Other Medically Important Condition),	n/a - n/a])		
											Pyrexia (n/a - Unknown - Other Medically Important Condition)			
	10010506700	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Not Specified	Male		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- 10010507000	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											C-reactive protein increased (n/a - Recovering/Resolving - Other Medically Important Condition),	.,,		
											Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
											N-terminal prohormone brain natriuretic peptide increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Troponin I increased (n/a - Recovering/Resolving - Other Medically Important Condition)			
	EU-EC- 10010507031	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
											Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	n/a - n/a])		
											Dysstasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Gait disturbance (n/a - Not			

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										Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Stress (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010507112	01/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	1{DF} - n/a])		
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010507211	01/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010507221	01/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Pharyngeal swelling (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	1{DF} - Intramuscular])		
EU-EC- 10010497497	31/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010497888	31/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	31/10/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Important Condition) Ear pain (1wk -	COMIRNATY	Not reported	ICSR
10010498112			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Ear pain (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Fatigue (n/a - Unknown -), Influenza like illness (1wk - Recovered/Resolved -),	1{DF} - n/a])		
										Pain in extremity (1wk - Recovered/Resolved -),			
										Pain in extremity (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -),			
										Retching (n/a - Unknown -), Vertigo (1wk -			
	31/10/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved -) Rash (2d - Recovered/Resolved		Not reported	ICSR
10010498114			Healthcare Professional	Economic Area	available	Years				-)	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN]		

											- Not applicable - [n/a3mL - Intramuscular])		
EU-EC- 10010498117	31/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010498129	31/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (2d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Dyspnoea (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Hypertension (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Somnolence (2d - Recovered/Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010498205	31/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010498285	31/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010494199	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Drug withdrawn - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010494460	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010494609	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Ma i e	No	Catarrh (5d - Recovered/Resolved -), Cough (5d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Nausea (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010494865		Spontaneous	Professional	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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010494878		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010494955	30/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010494968		Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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			Professional	Area						Headache (n/a - Recovered/Resolved -),	(S - n/a - n/a - [n/a - n/a - n/a])		
										Injection site pain (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10010495194	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010495260	30/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bone pain (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Diarrhoea (5d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -),	immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
										Pyrexia (5d - Recovered/Resolved -)			
EU-EC- 10010495391	30/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	<u>ICSR</u>
										Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	- [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010495511	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC-	20/10/2021	Chantanaous	Non	European	Not	12.17	Adult	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICCD
10010495518	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	remale	No	Intermenstrual bleeding (n/a - Recovered/Resolved -), Menstruation irregular (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	30/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Resolved -) Extensive swelling of	applicable - [n/a - 1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10010495529			Healthcare Professional	Economic Area	available	Years				vaccinated limb (5d - Recovered/Resolved -), Headache (0d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Recovered/Resolved -), Injection site induration (5d - Recovered/Resolved -),	1{DF} - n/a])		
										Injection site pain (5d - Recovered/Resolved -),			
										Injection site swelling (6d - Recovered/Resolved -),			
										Injection site warmth (5d - Recovered/Resolved -), Myalgia (2d -			
EU-EC-	30/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved -) Menstruation irregular (n/a -	COMIRNATY	Not reported	ICSR
10010495538			Healthcare Professional	Economic	available	Years	Specified			Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010495601		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010495711	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oligomenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010496229	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Unknown - Other Medically Important Condition)	2,		
EU-EC- 10010496928	30/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010497064	30/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (2d - Recovered/Resolved -), Body temperature increased (2d - Recovered/Resolved -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Fatigue (2d - Recovered/Resolved -),	1{DF} - Intramuscular])		
										recovered/resolved),			

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										Recovered/Resolved -), Headache (2d - Recovered/Resolved -),			
										Pain in extremity (2d - Recovered/Resolved -)			
EU-EC- 10010497273	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Chills (1d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (1d - Recovered/Resolved -)			
EU-EC- 10010497296	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Body temperature increased (n/a - Recovered/Resolved -),	immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
										Chills (n/a - Recovered/Resolved -),			
FUEC	20/10/2021	Cnontonoous	Licalthanus	Furancan	Not	12.17	Adalasaant	Mala	No	Diarrhoea (n/a - Recovered/Resolved -)	COMIRNATY	Not reported	ICCD
EU-EC- 10010497321	30/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	мане	No	Circulatory collapse (1min - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010497470	30/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010481813	29/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Myalgia (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10010481900	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			reressional	/ " כם							immunisation - n/a - [n/a - 30ug - Intramuscular])		
EU-EC- 10010482100	29/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Caused/Prolonged Hospitalisation)	(S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010482154	29/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
			Professional	Area						Pyrexia (n/a - Recovered/Resolved -)	(S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])		
EU-EC- 10010482156	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			Professional	Alea						Muscular weakness (n/a - Recovered/Resolved -),	immunisation - n/a - [n/a - 30ug - Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010482273	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),	prophylaxis - n/a - [n/a3mL - Intramuscular])		
										Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010482366	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperpyrexia (4d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICSR
										Oedema mouth (4d - Recovered/Resolved - Other Medically Important Condition)	- [n/a3mL - Intramuscular])		

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EU-EC- 10010482381	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle spasms (0d - Recovered/Resolved -), Paresis (0d - Recovered/Resolved -), Tetany (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010482806	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a - n/a])		
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010483475	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010483522	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010483566	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010484362	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (4d - Recovered/Resolved -), Musculoskeletal pain (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Nausea (4d - Recovered/Resolved -), Vomiting (1d -			
EU-EC- 10010484407	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Eye pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),			
										Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10010484558	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye swelling (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
	201/25 11 11									Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			122
EU-EC- 10010484634	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010484666	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	1{DF} - n/a])		

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EU-EC- 10010484991	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Inflammatory marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site hypoaesthesia (n/a - Unknown -) Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S C COVID-19 immunisation - Not	[QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a -	ICSR
										Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [n/a - 1{DF} - n/a])	n/a]), [SERTRALINE] (C - n/a - n/a - [n/a - .5{DF} - n/a]),	
										Vaccination site hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		[TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a])	
EU-EC- 10010485090	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Lower respiratory tract infection (0d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Sensation of foreign body (n/a - Unknown -)			
EU-EC- 10010485184	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Complication associated with device (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Decreased appetite (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Head injury (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010485234	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Deafness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a])	RELVAR ELLIPTA [FLUTICASONE FUROATE, VILANTEROL] (C - n/a - n/a - [n/a - n/a -	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a -	
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		n/a - n/a])	
										Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hemiparaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important			

						1		1		1			
										Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nerve compression (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 1001048571		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 1001048577		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (36d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048577		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048577		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048578	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 1001048580		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (0d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 1001048580		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048581		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (25d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048581		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (0d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 1001048582		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain lower (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 1001048594		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001048597		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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (2d -			
EU-EC-	29/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Recovered/Resolved -) Headache (n/a - Not	COMIRNATY	Not reported	ICSR

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10010486553			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010486572	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10010486578	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
			, reressional	7 11 00						Headache (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
EU-EC-	20/10/2021	Casatanasia	Non	Non	Nat	12.17	Not	Mala	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	TOZINAMEDANI	Not reported	TCCI
10010487259	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged	n/a - n/a])		
EU-EC- 10010487302	29/10/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Axillary pain (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN]	[FLUTICASONE PROPIONATE] (C -	ICSF
10010 107302			Professional	Economic Area	available	rears	Specifica			Carditis (n/a - Unknown - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d -	Asthma - n/a - [n/a -	
										Condition), Chest discomfort (2d -	n/a - Intramuscular])	[SALBUTAMOL, SALBUTAMOL MICRONIZED,	
										Recovered/Resolved -), Neck pain (n/a - Unknown -),		SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a -	
										Painful respiration (2d - Recovered/Resolved -),		n/a - n/a])	
										Palpitations (n/a - Unknown -			
										Troponin increased (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010487303	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				Area						Feeling abnormal (0d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	1,42		
										Muscular weakness (0d - Recovered/Resolved -),			
										Pallor (0d - Recovered/Resolved -),			
										Presyncope (0d - Recovered/Resolved -)			
EU-EC- 10010487439	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSF</u>
				71164						Menstruation delayed (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Menstruation irregular (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010487440	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Influenza (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Suspected COVID-19 (n/a - Not Recovered/Not Resolved -)	n/a - n/a])		
EU-EC- 10010487442	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [1d - n/a - n/a])	ICSI
										Dizziness (n/a - Recovering/Resolving - Other	n/a - n/a])		

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										Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Off label use (n/a - Unknown -),			
										Product use issue (n/a - Unknown -),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010487467	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010487531	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010487595	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	2(01) 1(4)		
EU-EC- 10010487606	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010487608	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Limb discomfort (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010487612	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abnormal faeces (0d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Chills (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010487652	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved -), Menstruation irregular (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- 10010487853	29/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Tachycardia (42d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	2011215		Professional	Area		45 :-			l.	Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - n/a - n/a])		-
EU-EC- 10010488015	29/10/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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			Professional	Economic Area						Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010488102	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haematochezia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010488137	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010488147	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010488485	29/10/2021	Spontaneous	Non Healthcare Professional	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 - Intramuscular])	[FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - 125ug - n/a]), [OMEPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - 10mg - n/a]), [VITAMINS NOS] (C - n/a -	ICSR
EU-EC- 10010488486	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010488514	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Peripheral swelling (24h - Recovered/Resolved -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010488636	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010488670	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovered/Resolved With Sequelae - Life Threatening), Chills (n/a - Recovered/Resolved With Sequelae - Life Threatening), Confusional state (n/a - Recovered/Resolved With Sequelae - Life Threatening), Dizziness (n/a - Recovered/Resolved With Sequelae - Life Threatening), Heart rate increased (n/a - Recovered/Resolved With Sequelae - Life Threatening), Hypoaesthesia (n/a - Recovered/Resolved With Sequelae - Life Threatening), Hypopnoea (n/a - Recovered/Resolved With Sequelae - Life Threatening), Hypopnoea (n/a - Recovered/Resolved With Sequelae - Life Threatening), Hypotension (n/a - Recovered/Resolved With Sequelae - Life Threatening), Pruritus (n/a - Recovered/Resolved With Sequelae - Life Threatening), Pruritus (n/a - Recovered/Resolved With Sequelae - Life Threatening), Pyrexia (n/a - Recovered/Resolved With Sequelae - Life Threatening), Syncope (n/a - Recovered/Resolved With Sequelae - Life Threatening), Syncope (n/a - Recovered/Resolved With Sequelae - Life Threatening), Throat tightness (n/a - Recovered/Resolved With Sequelae - Life Threatening), Vomiting (n/a - Recovered/Resolved With Sequelae - Life Threatening), Vomiting (n/a - Recovered/Resolved With Sequelae - Life Threatening),	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - n/a])	ICSR
EU-EC- 10010489145	29/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

29/10/2021	Chantanaous								-),	1{DF} - n/a])		
29/10/2021	Chantanaous								Myalgia (n/a - Not			
	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -) Abdominal pain (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSF
		Professional	Economic Area	available	Icais	Specified			Diarrhoea (1d - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d -		
									Dizziness (n/a - Recovered/Resolved -),	n/a - n/a])		
									Pallor (n/a - Unknown -),			
									Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
									Vision blurred (n/a - Unknown			
9/10/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved -),	[TOZINAMERAN]	Not reported	ICSR
		Professional	Area						Haemorrhage (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
									Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
29/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
		Professional	Area						Unknown -),	immunisation - Not applicable - [n/a -		
									Unknown -),	n/a - n/a])		
29/10/2021	Spontaneous		European	Not available	12-17 Years	Adolescent	Female	No	Cough (45min -		Not reported	ICSR
		Troressional	Area	available	rears				Dyspnoea (45min - Recovered/Resolved - Life	(S - COVID-19 immunisation - Not applicable - [2s -		
									Formication (45min -	Intramuscular - More in ICSR])		
									Hypotension (45min - Recovered/Resolved - Life			
29/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Child	Male	No	Multisystem inflammatory syndrome in children (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Alea						Caused/Prolonged Hospitalisation)	immunisation - n/a - [1d - 1{DF} - Intramuscular])		
29/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Shoulder injury related to vaccine administration (n/a -	[TOZINAMERAN]	Not reported	ICSR
			Area						Other Medically Important Condition)	immunisation - n/a - [n/a - n/a - Intramuscular])		
9/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Gait disturbance (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
		Troressional	/ II Cu						Headache (n/a - Not Recovered/Not Resolved -),	- n/a - [n/a - n/a - n/a])		
									Movement disorder (n/a - Not Recovered/Not Resolved -)			
29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (2mo - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
			71100						Viral infection (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} -		
9/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR
			Area						Medically Important Condition)	immunisation - Not applicable - [1d -		
29/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
		Professional	Area						Hospitalisation),	immunisation - Not applicable - [n/a -		
									Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
									Headache (n/a - Recovered/Resolved - Caused/Prolonged			
									Hospitalisation), Hemiparesis (n/a -			
									Recovered/Resolved - Caused/Prolonged			
·9	9/10/2021 9/10/2021 9/10/2021 9/10/2021 9/10/2021	9/10/2021 Spontaneous 9/10/2021 Spontaneous 9/10/2021 Spontaneous 9/10/2021 Spontaneous 9/10/2021 Spontaneous 9/10/2021 Spontaneous	Professional	Healthcare Professional European	Healthcare Professional European Reconomic Area Professional European Reconomic Area Professional Economic Area	Healthcare Professional Economic Area Not Healthcare Professional Prof	Healthcare Professional European Reconomic Area Not Professional Reconomic Professional Reconomic Professional Reconomic Area Not Professional Reconomic Professional Profe	Healthcare Professional European Professional Area Not Healthcare Professional Economic Area Not Specified Female Professional Female Female Not Specified Female Professional Female Not Specified Female	Healthcare Professional European Area Not Area Not Specified Female No Specified Not Specified Female No Specified Not Specified Not Specified Female No Specified Not Specified Female No Specified Not Specified Female No Specified Not Specified	Syncope (n/a - Recovered/Recoved - Other Recovered/Recovered/Recovered/Recovered/Recovered/Recoved - Other Recovered/Recoved - Other Recovered/Recovered - Other Recovered/Recov	Professional Pro	Professional Pro

										Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010490267		Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010490460	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010490513	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Clonus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010490666	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010490755		Spontaneous	Professional	European Economic Area	Not available		Not Specified	Female	No	Alopecia (n/a - Recovering/Resolving -) Pain in extremity (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), KAFTRIO 75 MG/50 MG/100 MG FILM-COATED TABLETS [TEZACAFTOR, ELEXACAFTOR, UYACAFTOR] (S - Cystic fibrosis carrier - Dose not changed - [n/a - 2{DF} - Oral]), KALYDECO 150 MG FILM-COATED TABLETS [IVACAFTOR] (S - Cystic fibrosis carrier - Dose not changed - [n/a - 1{DF} - Oral]) TOZINAMERAN TOZINAMERAN	Not reported Not reported	ICSR
10010491240			Healthcare Professional	European	available	Years	Specified			Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19		

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				Area							applicable - [1d - n/a - n/a])		
:U-EC- .0010491379	29/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
U-EC- 0010491383	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [AMOXICILLIN] (S - n/a - Dose not changed - [n/a -	Not reported	ICS
EU-EC-	29/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Nausea (n/a - Not	n/a - n/a]) COMIRNATY	[CARBOHYDRATES	ICS
0010491533		Ţ	Healthcare Professional	Economic	available	Years	Specified			Recovered/Not Resolved -), Pyrexia (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - n/a	NOS] (C - n/a - n/a -),	
										Recovered/Not Resolved -),	- [n/a - n/a - n/a])	[FAT] (C - n/a - n/a -),	
										Retching (n/a - Not Recovered/Not Resolved -)		[GLUCOSE, ANHYDROUS, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, CITRIC ACID, POTASSIUM CHLORIDE, SODIUM CHLORIDE, GLUCOSE, DISODIUM HYDROGEN CITRATE, SODIUM CHLORIDE] (C - n/a - n/a -),	
												[LAMOTRIGINE] (C - n/a - n/a -),	
												[LANSOPRAZOLE] (C - n/a - n/a -),	
												[LEVOCARNITINE] (C - n/a - n/a -),	
												[MINERALS NOS] (C - n/a - n/a -),	
												[POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -),	
												[SODIUM VALPROATE] (C - n/a - n/a -),	
												[TOPIRAMATE] (C - n/a - n/a -),	
U-EC-	20/10/2021	Spontaneous	Nam	European	Not	12-17	Adolescent	Famala	No	Circulatory collapse (n/a -	COMIRNATY	[VITAMINS NOS] (C - n/a - n/a -) Not reported	TO
0010491907	23/10/2021	Spontaneous	Healthcare	Economic Area	available	Years	Adolescent	remale		Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dyspnoea (9d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Pelvic venous thrombosis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Pulmonary embolism (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
:U-EC- .0010492001	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	IC
										Dyskinesia (1d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			

EU-EC- 10010492004 EU-EC- 10010492004 EU-EC- 10010492005 EU-EC- 10010492015 EU-EC- 10010492016 EU-EC-	RAN] 19 n - Not [1d -	ICSR
EU-EC- 10010492014 Spontaneous Healthcare Professional Economic Area Specified Female 29/10/2021 Spontaneous Healthcare Professional Economic Area Specified Female Specified Female Specified Female Specified Female Specified S	RAN] 19 n - Not [1d -	ICSR
EU-EC- 10010492004 Porcessional Professional Professional European Economic Area Non Professional Economic Area Non Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Reco	RAN] 19 n - Not [1d -	<u>ICSR</u>
EU-EC- 10010492015 EU-EC- 10010492036 EU-EC-	nr])	
10010492015		
EU-EC- 10010492036 29/10/2021 Spontaneous Non Healthcare Professional Non Healthcare Non Hea	RAN] 19 1 - Not	<u>ICSR</u>
Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not	RAN] 19 1 - Not	<u>ICSR</u>
Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not		
Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10010492066 Spontaneous Non Healthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Reconstruction Reconst	RAN] 19 1 - Not	<u>ICSR</u>
Musculoskeletal pain (n/a - Not n/a - n/a]) Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC- 10010492266 Spontaneous Non Healthcare Professional Room Professional Room Non Healthcare Professional Room Non Healthcare Professional Room Non Healthcare Professional Room Non Healthcare Room Non Non Healthcare Room Non Healthcare Room Non Healthcare Room Non Non Healthcare Room Non Healthcare Room Non Healthcare Room Non	RAN] 19 1 - Not	<u>ICSR</u>
Diarrhoea (n/a - n/a]) Recovering/Resolving - Other Medically Important Condition),		
Fatigue (1d - Recovered/Resolved - Other Medically Important Condition),		
Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC- 10010492397 Spontaneous Healthcare Professional European Economic Area Female Not 12-17 Not Female No Arthralgia (n/a - COMIRNATY Recovering/Resolving - Caused/Prolonged Hospitalisation), Graphical Professional Female Not Recovering/Resolving - Caused/Prolonged Hospitalisation), Graphical Professional Gra	RAN] 19 n - Not	<u>ICSR</u>
Back pain (n/a - n/a]) Recovering/Resolving - Caused/Prolonged Hospitalisation),		
Neck pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		
Weight decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC- 10010492467 Spontaneous Non Healthcare Professional Professional Professional Not Healthcare Professional Not Healthcare Professional Not Healthcare Professional Not Healthcare Professional Not Not Area Not 12-17 Adolescent Female No Menstrual disorder (84d - Unknown -) Menstrual disorder (84d - Unknown -) (5 - Immunis - n/a - n/a])	RAN] sation	<u>ICSR</u>
EU-EC- 10010492472 Spontaneous Non Healthcare Professional Real Pr	RAN]	<u>ICSR</u>
EU-EC- 29/10/2021 Spontaneous Non European Not 12-17 Adolescent Male No Epistaxis (11d - COMIRNATY 10010492473 Economic available Years Recovering/Resolving -) [TOZINAMER		<u>ICSR</u>
Professional Area Area Recovering/Resolving -) [IOZINAVIEW Area Area	sation	

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EU-EC- 10010492474	29/10/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Depression (6d - Unknown -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Influenza (3d - Recovered/Resolved -), Injection site erythema (7d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (3d - Recovered/Resolved -)			
EU-EC- 10010492475	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492478	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (89d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010492480	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492481	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492482	29/10/2021	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 - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492483	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (86d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492484	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492486	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Furuncle (55d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492521	29/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010492523		Spontaneous	Healthcare Professional	Economic Area	Not available	12-17 Years	Adolescent		No	Chills (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Myalgia (0d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Paraesthesia (0d - Recovered/Resolved -), Tinnitus (0d - Recovered/Resolved -) Artivated partial	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493415		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Activated partial thromboplastin time prolonged (n/a - Recovered/Resolved - Other Medically Important Condition), Petechiae (n/a - Recovered/Resolved -), Prothrombin time prolonged (n/a - Recovered/Resolved - Other Medically Important Condition), Rash maculo-papular (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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EU-EC- 10010493474	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493791	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (49d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493793	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493794	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Alopecia (35d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493796	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493797	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (84d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493798	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypertension (0d - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493799	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovering/Resolving -), Feeling hot (1d - Recovering/Resolving -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovering/Resolving -), Rash (1d - Recovered/Resolved -), Stress urinary incontinence (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493800	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Depression (6d - Unknown -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Influenza (3d - Recovered/Resolved -), Injection site erythema (7d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493801	29/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493802	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (28d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493803	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (36d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493804		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Hypoaesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010493805		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010493810	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010493916	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Fall (n/a - Unknown -), Hypopnoea (n/a - Unknown -	applicable - [n/a - n/a - n/a])		
										Palpitations (n/a - Unknown -			
										Presyncope (n/a - Unknown -),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Visual impairment (n/a - Unknown -)			
EU-EC- 10010493972	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a])		
EU-EC- 10010468405	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (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- 10010468408	28/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Arthralgia (2d - Recovered/Resolved -), Chills (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovered/Resolved -), Fatigue (2d -	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Resolved -), Headache (2d -			
										Recovered/Resolved -), Malaise (2d - Recovered/Resolved -),			
										Mastitis (n/a - Recovering/Resolving -),			
										Myalgia (2d - Recovered/Resolved -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010468453	28/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (4d - Recovered/Resolved -), Vaccination site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010468458	28/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (14d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL -	Not reported	ICSR
EU-EC- 10010468491	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				7.1.54						Injection site pain (n/a - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010468842	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010469046	28/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (5d - Recovered/Resolved -), Photophobia (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010469151	28/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
10010 109131			Professional		available	rears	Specifica			recestered/not resource /	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010469214	28/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Heavy menstrual bleeding (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010469346	28/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (7d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Headache (7d - Recovered/Resolved -), Vomiting (7d -	(S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC-	28/10/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Recovered/Resolved -) Balance disorder (n/a -	TOZINAMERAN	Not reported	ICSR
10010469517	1	1	Healthcare	European	available	Years	Specified	1		Unknown - Life Threatening,	[TOZINAMERAN]	I	

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				Professional	Economic Area						Caused/Prolonged Hospitalisation), Coordination abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Diplopia (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
											Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Guillain-Barre syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Haemoptysis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Hypersensitivity (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
											Hypoaesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Inappropriate schedule of product administration (n/a - Unknown -),			
											Influenza like illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Miller Fisher syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Paraesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Rash (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
											Rhinorrhoea (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Speech disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)			
	EU-EC- 10010469522	28/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
											Extra dose administered (n/a - Unknown -), Off label use (n/a - Unknown -	n/a - Intramuscular])		
), Rash (n/a - Recovered/Resolved - Other			
	EU-EC- 10010470351	28/10/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Medically Important Condition) COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
					Area						Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
	EU-EC- 10010470445	28/10/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
	EU-EC- 10010470820		Spontaneous	Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Amnesia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
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				Area						Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [1d - n/a - n/a])		
										Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010470866	28/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Cold sweat (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rhinitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010471190	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Deep vein thrombosis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010471212	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Pain in extremity (2d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010471285	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010471336	28/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010471449	28/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC-	28/10/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Ma l e	No	Other Medically Important Condition) Fall (n/a - Recovered/Resolved	.3mL - Intramuscular])	Not reported	ICSR
10010471508	20, 10, 2021	Spontanious	Professional		available	Years	Specified			-), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		1331.
										Condition), Presyncope (n/a -	iliya iiyaji		
EU-EC- 10010471513	28/10/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Chest discomfort (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Chest pain (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Pulse waveform abnormal (n/a - Unknown -),			
EU-EC-	28/10/2021	Spontaneous	Non	European	Not	12-17	Adult	Female	No	Respiration abnormal (n/a - Unknown -) Chest pain (n/a - Not	COMIRNATY	Not reported	ICSR
10010471590	20, 10, 2021	Sportuneous	Healthcare Professional	Economic	available	Years	Audit	. Gride		Recovered/Not Resolved -), Dyspnoea (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not	oc reported	icsk.
										Recovered/Not Resolved -), Influenza like illness (n/a -	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Resolved -), Injection site pain (n/a -			
										Unknown -), Pericarditis (n/a - Not			
						<u> </u>			<u> </u>	Recovered/Not Resolved -)			

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