

Line Listing Report
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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration PT - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10010986554	16/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010968305	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010661990	16/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Death (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(DF) - Intramuscular])	Not reported	ICSR
EU-EC-10010632312	12/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening), Decreased appetite (n/a - Fatal - Results in Death, Life Threatening), Headache (n/a - Fatal - Results in Death, Life Threatening), Myocarditis (n/a - Fatal - Results in Death, Life Threatening), Pyrexia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 (DF) - n/a])	Not reported	ICSR
EU-EC-10010620335	11/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bronchospasm (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010607769	10/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010236495	06/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	ADAMTS13 activity decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010093552	22/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009815542	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009743215	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009305404	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiomegaly (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pericardial effusion (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008822508	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])	[CRISABOROLE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transplacental]), [LORATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR