Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Case Line Listing

You searched for the following:

Reaction Outcome: Fatal
Study Type: Unknown,Other studies
Patient Age Group: Child,Adolescent
Characterisation: Suspect,Interacting
Trade Name: COMIRNATY COVID-19 vaccine,COVID-19 Vaccine (TNS),Spikevax COVID-19 vaccine - (elasomeran),COMIRNATY Original/Omicron BA (TNS) COVID-19 Vaccine - (tozinameran/not specified),COMIRNATY ORIGINAL/OMICRON BA.1 COVID-19 Vaccine - (tozinameran/riltozinameran),COMIRNATY ORIGINAL/OMICRON BA.4-5 COVID-19 Vaccine - (tozinameran/famtozinameran),COVID-19 Vaccine AstraZeneca,NUVAXOVID COVID-19 Vaccine,SPIKEVAX BIVALENT (TNS) ORIGINAL/OMICRON COVID-19 vaccine - (elasomeran/not specified),Spikevax Bivalent Original / Omicron COVID-19 vaccine - (elasomeran/imelasomeran),SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 COVID-19 vaccine - (elasomeran/davesomeran)

Number of Reports: 17

The information provided in the following table is from reports included in the Adverse Event Management System (TGA's internal adverse event database). The decision reason is provided for reports that do not appear in the DAEN – medicines, and these cases are identified by the blue shading. The other cases are included in the Database of Adverse Event Notifications (DAEN) – medicines. Inclusion in the DAEN – medicines does not mean that the details of the event have been confirmed, or that the event has been determined to be related to a COVID-19 vaccine.

Limitations of the data

This document contains information from reports of adverse events that the TGA has received in relation to therapeutic goods. It does not contain all known information, and an assessment of the safety of a medicine cannot be made based on this information.

Causality

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. The reporter may be a health professional, a sponsor, or a member of the public.
- Adverse events are suspected of being related to a therapeutic good, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.

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Case no.	Report Date	Sex	Age	Medicine (Onset Time in Days)	Reaction	Decision reason for rejected cases (blue highlight)
734187	10/05/2022	Male	5	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Abdominal pain; Cardiac arrest; Eosinophilia; Eosinophilic myocarditis	
734749	12/05/2022	Male	5	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Cardiac arrest	Duplicate report
724925	28/03/2022	Male	6	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Adverse event following immunisation	Causality unassessable/ unclassifiable (hoax report)
696384	18/01/2022	Male	7	COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspect [redacted]	Adverse event following immunisation	Causality unassessable/ unclassifiable (hoax report)
719838	11/03/2022	Male	7	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Cardiac arrest; Generalised tonic-clonic seizure	
763500	3/01/2023	Male	7	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Cardiac arrest	Duplicate report
724023	25/03/2022	Female	9	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Cardiac arrest	
725202	29/03/2022	Female	9	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Cardiac arrest	Duplicate report
733723	6/05/2022	Male	10	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Adverse event following immunisation	
647663	20/10/2021	Female	14	Spikevax COVID-19 vaccine - (elasomeran) (elasomeran) - Suspect [redacted]	Brain injury; Cardiac arrest; Dizziness; Encephalitis; Headache; Multiple organ dysfunction syndrome; Nausea; Pyrexia	
744306	11/07/2022	Female	14	Spikevax COVID-19 vaccine - (elasomeran) (elasomeran) - Suspect [redacted]	Immunisation reaction	
695048	15/01/2022	Male	15	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Adverse event following immunisation; Head banging	

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Case no.	Report Date	Sex	Age	Medicine (Onset Time in Days)	Reaction	Decision reason for rejected cases (blue highlight)
744924	15/07/2022	Unspecified	15	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect (-); Spikevax COVID-19 vaccine - (elasomeran) (elasomeran) - Suspect [redacted]	Adverse event following immunisation	No longer a valid report
616124	2/09/2021	Male	17	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Headache; Malaise; Viral myocarditis	
627336	19/09/2021	Male	17	COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified)) - Suspect [redacted]	Adverse event following immunisation	Duplicate report
690348	6/01/2022	Male	17	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted]	Headache; Myocarditis; Oropharyngeal pain	Duplicate report
762472	20/12/2022	Female	17	COMIRNATY COVID-19 vaccine (tozinameran) - Suspect [redacted] Trade Name Not Specified (Etanercept) - Concomitant [redacted] Trade Name Not Specified (amitriptyline) - Concomitant [redacted] Trade Name Not Specified (azathioprine) - Concomitant [redacted] rade Name Not Specified (buprenorphine) - Concomitant [redacted] Trade Name Not Specified (paracetamol) - Concomitant [redacted] Trade Name Not Specified (piroxicam) - Concomitant [redacted] rade Name Not Specified (prednisolone) - Concomitant [redacted] Vitamin D3 (colecalciferol) - Concomitant [redacted] Zoledronate (zoledronic acid monohydrate) - Concomitant [redacted]	Arrhythmogenic right ventricular dysplasia; Escherichia sepsis; Vomiting	