Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

Date report received:

Notification ID:

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

National Adverse Events Following Immunisation (AEFI) reporting form

Vaccinated person's details					
Personal details					
Surname:		First name:			
Sex:	Unknown	Date of Birth:	**or** Age: Years Months		
Street address:					
Suburb:		State:	NT	Postcode:	
Phone:		Email:			
Name of parent/guardian: (if relevant)					
Indigenous status: Is the person of Aboriginal or Torres Strait Islander origin?	Yes, Both Aboriginal and Torres Stra				
What is the Ethnicity of the person?					
Vaccination provider details					
Surname:		First name:			
Street address:					
Suburb:		State:	NT	Postcode:	
Phone:		Email/Fax:			
Profession: Clinical Setting:	Other, Please Specify Aged Care Facility				

Vaccinated person additional details			
Was the vaccinated person pregnant at the time of vaccination?	Unknown		
Has the vaccinated person ever been diagnosed with COVID-19?	Unknown	If Yes when was this?	
Has the vaccinated person had previous reactions to vaccinations?	Unknown	What happened?	
Does the vaccinated person have any allergies? (please provide details)			
Past medical history:(please provide details of any medical history including details of previous vaccination reactions)			

Adverse event details			
Onset of event	Date:		Time:
Please describe the events, including timeline of occurrences:			

Who treated the reaction?	Other, please specify
Please tell us about the treatment/care provided? (eg antibiotics, adrenaline, advice, counseling etc	
Please tell us about the medications and/or vaccines the person has had in the last 4 weeks	
Was the person sick when they had the vaccination?	Unknown
Has this report been sent to others?	Unknown
How many vaccines did the person have together?	more than 6

Outcome

Have the symptoms resolved?	☐ **Yes** - By what time had they resolved? **Date:** **Time:** ☐ **No** - Symptoms are ongoing as of: **Date:** **Time:** Please describe ongoing symptoms: ☐ **Unknown**

Additional details

Date of report:		Reporter type:	Other: Please sp

Vaccine (brand name)	Dose no.	Batch no.	Date given	Time given	Route of administration	Injection site
					Not sure	Not Applicab
					Not sure	Not Applicab
					Not sure	Not Applicab
					Not sure	Not Applicab
					Not sure	Not Applicab
					Not sure	Not Applicab

Reporter details

☐ As per vaccinated person's details (above) ☐ As per vaccination provider details (above)

or Details below

Surname:		First name:	
Practice name: (if relevant)			
Street address:			
Suburb:		State: NT	Postcode:
Phone:		Email:	

Consent statement

I, the reporter, agree to be contacted for further follow up regarding this adverse event if necessary.

☑ Yes ☐ No

Signature/initials* Date

Please advise the parent/patient that contact details will be used to follow up if information is needed.

** For verbal reports indicate how consent was obtained*

Once completed, submit or send to the TGA Click to Submit

- By mail to: Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606
- By fax to: 02 6232 8392

  By email to: adr.reports@tga.gov.au

Click to Print Click to Save file

Privacy statement

Health Professionals reporting on behalf of a patient should provide the patient with a copy of this privacy statement.

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The Therapeutic Goods Administration (the TGA) is part of the Department of Health. The TGA can be contacted by phone on 1800 020 653, by email at info@tga.gov.au, or by post at PO Box 100, Woden ACT 2606, Australia.

Information in this report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports of AEFIs are assessed and entered into the TGA's Australian Adverse Drugs Reactions System (the ADRS).

The TGA collects personal information relating to adverse events following immunisation (AEFIs). At times, this information is collected from someone other than the individual to whom the personal information relates. This can occur when AEFIs are reported to a person or an entity other than the TGA (such as a health professional), and that person or entity passes the information on to the TGA (either directly or through a State or Territory health agency).

Collection of personal information from sponsors of therapeutic goods is required or authorised under Chapter 3 of the Act.

Personal information about patients is collected and used to:

- Assess the safety of vaccines under the Act.
- Contact the reporter (if additional information is needed to evaluate the reported adverse events).
- Check that the same information has not been received multiple times for the same adverse event.
- Contact representatives of entities that supply therapeutic goods, to discuss reported adverse events.

Personal information collected in this report may be disclosed by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). For reports related to vaccine events, personal information about the reporter or the patient may be disclosed to State and Territory health agencies under subsection 61(3) of the Act.