Australian Government

Department of Health

Therapeutic Goods Administration

TGA use only

Report of suspected adverse reaction to medicines or vaccines

See statement about the collection and use of personal information overleaf, and please attach any additional data to this form

Patient initials or medical record number:	Sex: M ☐ F ☐ Weight (kg):	Date of birth or age:

Suspected medicine(s)/vaccine(s)

Medicine/vaccine (please use trade names; include batch number and AUST R or AUST L number if known)	**Dosage** (Dose number for vaccines eg 1st DTP)	Date begun	Date stopped	Reason for use

Other medicine(s)/vaccine(s) taken at the time of the reaction

Medicine/vaccine	**Dosage**	Date begun	Date stopped	Reason for use

Reaction(s): Date of onset of reaction (for vaccines time after administration): / /

Describe: (please provide as much detail as possible and include any results of relevant laboratory data and other investigations)

Seriousness: Life threatening ☐ Hospitalised ☐ Required a visit to doctor ☐

Treatment of reaction:

Outcome: Recovered ☐ ▸ Date: / / | Not yet recovered ☐ | Fatal ☐ ▸ Date: / / | Unknown ☐

Sequelae? No ☐ Yes ☐ ▸ Describe:

Reporting: Doctor ☐ Pharmacist ☐ Other ☐

Name:

Address:

Postcode:

Contact details (email or phone)

Signature:

Date: / /

Thank you for taking the time to complete this form

PTO

Report of suspected reaction to medicines or vaccines ("Blue card")

Privacy statement

For general privacy information, go to <www.tga.gov.au/privacy>.
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 are entered into the Therapeutic Goods Administration's (TGA's) Adverse Event Management System (AEMS). Further information about how the TGA uses adverse event information that is reported to it is available at <www.tga.gov.au/reporting-adverse-events>.

The TGA collects personal information in this report to:

- monitor the safety of medicines and vaccines under the Act
- contact the reporter of the adverse event if further information is required
- contact representatives of entities that supply therapeutic goods, to discuss reported adverse events
- check that the same information has not been received multiple times for the same adverse event.

At times, this information is collected from someone other than the individual to whom the personal information relates. This can occur when an adverse event is reported to a person or an entity other than the TGA (such as a health professional, a hospital or a sponsor), and that person or entity passes the information on to the TGA. In those cases, ordinarily the TGA will not collect the name and contact details of patients. However, the TGA may collect other information relating to patients, including the date of birth or age, gender, weight, initials and information about the relevant adverse event.

Personal information collected in this report may be disclosed as permitted under the Privacy Act 1988, including by consent or where the disclosure is required by, or authorised under, a law (for example, under section 61 of the Act). Where a report relates 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.

Fold here first (Please do not use staples on this form)

www.tga.gov.au/reporting-problems Email: adr.reports@tga.gov.au Fax: 02 6232 8392

What to report

You do not need to be certain, just suspicious!

Any information related to the reporter and patient identifiers is kept strictly confidential.
Adverse drug reaction reports should be submitted for prescription medicines, vaccines, over-the-counter medicines (medicines purchased without a prescription), and complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals).
Please include timing of reactions relative to medicine administration where relevant.
The TGA particularly requests reports of:

- All suspected reactions to new medicines and vaccines
- All suspected drug interactions
- Unexpected reactions, that is not consistent with product information or labelling
- Serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs, and birth defects.

Fold here second

D1073 June 2018

Delivery Address:
PO Box 100
WODEN ACT 2606

No stamp required
if posted in Australia

Medicines Safety Monitoring
Pharmacovigilance and Special Access Branch
Reply Paid 100
WODEN ACT 2606