Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office use only

Report of suspected adverse reaction to medicines or vaccines

(See statement about the collection and use of personal information overleaf)
Please attach any additional data to this sheet

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

Suspected medicine(s)/vaccine(s)
(please use trade names; include **AUST R or AUST L number** for non-prescription medicines, and batch number (if known)

Medicine/vaccine	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 (or for vaccines time after administration): / /

Describe: (please provide as much detail as possible and include any results of relevant supportive 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:

Comments (eg relevant history, allergies, previous exposure to this medicine):

Reporting ❑ doctor, ❑ pharmacist, ❑ other: Name: Address:	Contact details (email or phone)
Postcode:	Signature Date: / /

Thank you for taking the time to complete this form

Further information/other comments:

Please note: The personal information in this form is collected and used for the purpose of assessing the safety of medicines under the Therapeutic Goods Act 1989. The personal information is only disclosed: (i) to State and Territory Health Departments (if the information relates to Immunisation Schedule vaccine events); or (ii) where there is a legal requirement to disclose it. The reporter’s details are recorded in the database so that reporters can be contacted if further information is required.

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www.tga.gov.au/problem Email: adr.reports@tga.gov.au Phone: 1800 044 114 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 indicate 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, ie 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

All reports are assessed by a health professional and entered into the Australian Adverse Drug Reactions System (ADRS).

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Delivery Address:
PO Box 100
Woden ACT 2606

No stamp required
if posted in Australia

Medicines Safety Monitoring
Reply Paid 100
WODEN ACT 2606