

Suspected adverse drug reaction reporting form

The adverse drug reaction MUST pertain to an identifiable patient. Fill in as much details as are possible – the patient particulars, nature of event and the names of suspect drug(s) are the minimum necessary.

REPORTER'S IDENTITY WILL REMAIN CONFIDENTIAL

What to report: Report all reactions to recently introduced drugs and / or uncommon or severe reactions to older drugs. Also report reactions to vaccines and all suspected drug interactions resulting in ADRs.

A reaction is to be regarded as **SERIOUS** if it is fatal, life-threatening, permanently or significantly disabling or incapacitating, requires or prolongs hospitalization or requires intervention to prevent one of the above consequences. Events that are in the nature of birth defects are also serious.

Patient's name: _____

Age: _____ [] years [] months [] days **Sex:** [] Male [] Female **Weight:** _____ kg

If hospitalized, Name of hospital: _____

Address of hospital: _____

Reg. No.: _____ **Ward and Bed no.:** _____ **Admission date:** _____

Suspected adverse drug reaction (ADR) – State diagnosis (if known) or principal sign-symptoms:

Date of onset: _____ **Date of resolution:** _____

Severity of ADR:

- Mild
- Moderate
- Severe

Can it be regarded as a serious ADR

- Yes
- No

Outcome of ADR:

- Recovered without sequelae
- Recovered with sequelae
- Not yet recovered
- Died due to adverse reaction
- Died, drug may be contributory
- Died, unrelated to drug
- Unknown

Suspect drug(s): Drug or drugs suspected to have caused the adverse event in question with a reasonable possibility of a causal relation to it. Give generic name, brand name and lot number, if known, in the 'Name' column.

Name	Route	Dose regimen	Start date	Stop date	Indication

Concomitant drug(s): Other drugs (including self-medication and over-the-counter medication) being received by the patient at the time of taking the suspect drug or taken in the last 3 months. Give generic name, brand name and lot number, if known, in the 'Name' column.

Name	Route	Dose regimen	Start date	Stop date	Indication

Additional information: Relevant additional information including medical history, investigations, known allergies and suspected drug interactions. For congenital anomalies and events during pregnancy, state all other drugs taken and the LMP if known.

Reported by:

Name: _____

Designation: Doctor Pharmacist Nurse Other healthcare provider Other (specify) _____

Address: _____

Phone: _____ Fax: _____ E-mail: _____

**Please fill-in the online version of this form or fill-in the print version and mail it to:
CDMU Documentation Centre, 47/1B Garcha Road, Kolkata – 700 019, India.**

This form has been Modeled on the POSTAL ADR MONITORING FORM of the National Pharmacovigilance Centre,
Department of Pharmacology, All India Institute of Medical Sciences, New Delhi-110029.
We will periodically forward reports accumulated by us to the National Pharmacovigilance Centre.