DEPARTMENT OF PHARMACOLOGY, AIIMS BHOPAL

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Ph: 0755-2902620 Email: adr@aiimsbhopal.edu.in

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

Patient ID:	**INDIAN PHARMACOPOEIA COMMISSION** (National Coordination Center- Pharmacovigilance programe of India) Ministry of health & Family Welfare Government of India Sector-23, Rai Nagar, Gaziabad-201002	**(AMC/ NCC Use only)** AMC Report No: Worldwide Unique ID:

A. PATIENT INFORMATION

***1.** Patient Initials

2. Age at time of event or date of birth

3. Sex M F

4. Weight_____ Kgs

12. Relevant tests / laboratory data with dates

B. SUSPECTED ADVERSE REACTION

***5.** Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

***7.** Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction

- ☐ Death (dd/mm/yyyy
- ☐ Life threatening
- ☐ Hospitalization/prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

***15.** Outcomes

- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)

C. SUSPECTED MEDICATION(S)

S.No	***8.** Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if kknown)	Exp. Date (if known))	Dose used	Route used	Frequency	Therapy dates (if known, give duration)		Reason for use / prescribed for
								Date Started	Date Stoppe	
i.										
ii.										
iii.										
iv.										

S.No As per C	**9.** Reaction abated after drug stopped or dose Reduced					**10.** Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

***11.** Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. REPORTER (see confidentiality section on first page)

***16.** Name and Professional Address :

Pin code:_____

E-mail Tel. No. (with STD code):

Occupation_____Signature

17. Causality Assessment

***18.** Date of this report (dd/mm/yyyy)

*** These details are essential.**

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**

- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**
  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage

- **Report even if:**
  - You're not certain the product caused adverse reaction
  - You don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.

- **Who can report:**
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

- **Where to report:**
  - Please return the completed form to the
    Adverse Drug Reaction Monitoring Centre
    Department of Pharmacology
    AIIMS, Bhopal.
    Ph: 0755 – 2902620
    Email: adr@aiimsbhopal.edu.in

Name of receiver:

Suspected Adverse Drug Reaction Reporting Form

For VOLUNTARY reporting
of suspected adverse drug reactions by
health care professionals

सत्यमेव जयते

IPC

National Coordinating Centre
Pharmacovigilance Programme of India
India Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.:0120-2783400, 2783401, 2783392,
FAX: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex-pected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.**