# Suspected Adverse Drug Reaction Reporting Form

**For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals**

**CDSCO**  
Central Drugs Standard Control Organization  
Directorate General of Health Services,  
Ministry of Health & Family Welfare, Government of India,  
FDA Bhavan, ITO, Kotla Road, New Delhi  
www.cdsco.nic.in

### A. Patient Information

<table>
<thead>
<tr>
<th>1. Patient Initials</th>
<th>2. Age at time of Event or date of birth</th>
<th>3. Sex</th>
<th>4. Weight Kg</th>
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</thead>
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### B. Suspected Adverse Reaction

<table>
<thead>
<tr>
<th>5. Date of reaction stated (dd/mm/yyyy)</th>
<th>6. Date of recovery (dd/mm/yyyy)</th>
<th>7. Describe reaction or problem</th>
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<tbody>
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</table>

### C. Suspected medication(s)

<table>
<thead>
<tr>
<th>S.No</th>
<th>8. Name (brand and/or generic name)</th>
<th>Manufacturer (if known)</th>
<th>Batch No./ Lot No. (if known)</th>
<th>Exp. Date (if known)</th>
<th>Dose used</th>
<th>Route used</th>
<th>Frequency</th>
<th>Therapy dates (if known give duration)</th>
<th>Reason for use of prescribed for</th>
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<tbody>
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<td>Date started</td>
<td>Date stopped</td>
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</table>

### D. Reporter (see confidentiality section in 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)
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 nearest Adverse drug reaction Monitoring Centre (AMC) or to National Coordinating Centre
   • A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm

• What happens to the submitted information:
   • Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
   • The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
   • The information is submitted to the Steering Committee of PvPI constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

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Pharmacovigilance Programme of India
for Assuring Drug Safety

Pharmacovigilance Programme of India (PvPI)
National Coordinating Centre,
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

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.