**SUSPECTED ADVERSE DRUG REACTION REPORTING FORM**

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

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**A. PATIENT INFORMATION**

1. Patient Initials: 

2. Age at time of Event or date of birth: 

3. Sex: □ M  □ F

4. Weight ___ Kgs

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**B. SUSPECTED ADVERSE REACTION**

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

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

7. Describe reaction or problem

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

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**C. SUSPECTED MEDICATION(S)**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Name (brand and/or generic name)</th>
<th>Manufactur (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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Date started</td>
<td>Date stopped</td>
</tr>
</tbody>
</table>

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**D. REPORTER (see confidentiality section on first page)**

16. Name and Professional Address: 

17. Causality Assessment

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

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**AMC Report No.**

Worldwide Unique
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://ipc.nic.in and also 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.

Suspected Adverse Drug Reaction Reporting Form

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

National Coordinating Centre
Pharmacovigilance Programme of India
India Pharmacopeia 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.