

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

<p>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</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="text-align: right; font-weight: bold; font-size: small;">(AMC/ NCC Use only)</td> </tr> <tr> <td>AMC Report No. _____</td> </tr> <tr> <td>Worldwide Unique no. _____</td> </tr> </table>	(AMC/ NCC Use only)	AMC Report No. _____	Worldwide Unique no. _____									
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<p>B. Suspected Adverse Reaction</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">5. Date of reaction stated (dd/mm/yyyy)</td> <td rowspan="3" style="width:50%; vertical-align: top;">13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)</td> </tr> <tr> <td>6. Date of recovery (dd/mm/yyyy)</td> </tr> <tr> <td>7. Describe reaction or problem</td> </tr> </table>	5. Date of reaction stated (dd/mm/yyyy)	13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)	6. Date of recovery (dd/mm/yyyy)	7. Describe reaction or problem	<p>14. Seriousness of the reaction</p> <table style="width:100%;"> <tr> <td><input type="checkbox"/> Death (dd/mm/yyyy)_____</td> <td><input type="checkbox"/> Congenital anomaly</td> </tr> <tr> <td><input type="checkbox"/> Life threatening</td> <td><input type="checkbox"/> Required intervention to prevent permanent impairment / damage</td> </tr> <tr> <td><input type="checkbox"/> Hospitalization-initial or prolonged</td> <td><input type="checkbox"/> Other (specify)</td> </tr> <tr> <td><input type="checkbox"/> Disability</td> <td></td> </tr> </table>	<input type="checkbox"/> Death (dd/mm/yyyy)_____	<input type="checkbox"/> Congenital anomaly	<input type="checkbox"/> Life threatening	<input type="checkbox"/> Required intervention to prevent permanent impairment / damage	<input type="checkbox"/> Hospitalization-initial or prolonged	<input type="checkbox"/> Other (specify)	<input type="checkbox"/> Disability	
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<p>15. Outcomes</p> <table style="width:100%;"> <tr> <td><input type="checkbox"/> Fatal</td> <td><input type="checkbox"/> Recovering</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td><input type="checkbox"/> Continuing</td> <td><input type="checkbox"/> Recovered</td> <td><input type="checkbox"/> Other (specify)_____</td> </tr> </table>		<input type="checkbox"/> Fatal	<input type="checkbox"/> Recovering	<input type="checkbox"/> Unknown	<input type="checkbox"/> Continuing	<input type="checkbox"/> Recovered	<input type="checkbox"/> Other (specify)_____						
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C. Suspected medication(s)

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

Sl.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.										

<p>11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)</p>	<p>D. Reporter (see confidentiality section in first page)</p> <p>16. Name and Professional Address : _____ _____ Pin code : _____ E-mail _____ Tel. No. (with STD code): _____ Occupation _____ Signature _____</p>
	<p>17. Causality Assessment</p>
	<p>18. Date of this report (dd/mm/yyyy)</p>

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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Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India
FDA Bhawan, ITO Kotla Road, New Delhi – 110002
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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 expected 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.**