ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report Serious adverse events. An event 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 event
  - you don't have all the details although point nos. 1, 5, 8, 11, 20 & 22 (see reverse) are essentially required.
- **Who can report:**
  - any health care professional (Doctors including Dentists, Nurses, and Pharmacists).
- **Where to report:**
  - after completing, please return this form to the same Pharmacovigilance Centre from where you received.
  - a list of country vide Pharmacovigilance Centres is available at www.cdsco.nic.in.
  - in any case of doubt, you may send this form to the National Pharmacovigilance Centre at: Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110 011.
- **What happens to the submitted information submitted:**
  - the information provided in this form is handled in strict confidence. Peripheral Pharmacovigilance will forward this form to the Regional Pharmacovigilance Centres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally the data is statistically analysed and forwarded to the global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - the data is periodically reviewed by the National Pharmacovigilance Advisory Committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with responsibility to review the data and suggest any interventions that may be required.

Adverse Drug Event Reporting Form

For VOLUNTARY reporting of adverse drug events by health care professionals

सत्यमेव जयते

CDSCO

Central Drugs Standard Control Organisation
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India.
Nirman Bhawan, New Delhi 110011
www.cdsco.nic.in

ATTENTION

HEALTH CARE PROFESSIONALS

Your **5 Minutes**

Can Help Us

Ensure Safer Medications

CDSCO

Central Drugs Standard Control Organisation
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
Nirman Bhawan, New Delhi 110 011
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Adverse Drug Event Reporting Form

For VOLUNTARY reporting of Adverse Drug Events by health care professionals

Report #

To filled in by Pharmacovigillance centres receiving the form

A. Patient information

1. Patient identifier initials (First, last) ____ ____
Date of birth:

2. Age at time of event: _____
or
_____ (dd/mm/yy)

3. Sex ☐ F ☐ M

4. Weight _____ kgs

B. Suspected Adverse Event

5. Outcomes attributed to adverse event (check all that apply)

- ☐ death _____ (dd/mm/yy)
- ☐ life-threatening
- ☐ hospitalization — initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: _____

6. Datesof event starting (dd/mm/yy)

7. Dates of event stopping (dd/mm/yy)

8. Describe event or problem

9. Relevant tests/laboratory data, including dates

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

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to & 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 event.

C. Suspect medication(s)

11. Name (Brand and/or generic name)	(Labeled Strength)	(Manufacturer)
#1		
#2		

12. Dose	Frequency	Route used	13. Therapy dates (if unknown, give duration) From (dd/mm/yy)	To (dd/mm/yy)
#1			#1	
#2			#2	

14. Diagnosis for use (separate indications with commas)
#1
#2

15. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ Not Applicable

16. Lot # (if known)	Exp. date (if known)
#1	#1
#2	#2

17. Event reappeared after reintroduction
#1 ☐ yes no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ Not Applicable

18. Concomitant medical products and therapy dates including self medication & herbal remedies (exclude those used to treat event)

D. Clinician (if not the reporter)

19. Name and Professional Address: _____

_____

_____ Pin code: _____

Tel No.: _____ Speciality: _____
With STD code

E. Reporter (see confidentiality section below)

20. Name & Address:

Phone#

21. Date of this report (dd/mm/yy)

22. Health professional? ☐ yes ☐ no

23. Occupation

24. Also reported to
- ☐ no one else
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

25. If you do not want your identity disclosed to the manufacturer, place an "x" in this box. ☐