ADVERSE DRUG REACTION (ADR) REPORTING FORM

VENUS REMEDIES LIMITED
Plot No. 51-52, Industrial Area, Phase – 1,
Panchkula (Hry.), 134 113, India
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E-mail : **pharmacovigilance@venusremedies.com**

for VENUS Use only
Report No. _____
Date :

Report Type : ☐ Initial ☐ Follow – up ☐ Adverse Event ☐ Product Complaint ☐ Both

A. Patient Information

1. **Patient Initials** _____
2. **Age (or) Date of Birth** _____
3. **Sex** : ☐ M ☐ F
4. **Weight** (Kgs) **:** _____

B. Adverse Drug Reaction / Event

5. **Date of Onset** (dd/mm/yyyy):
6. **Date of resolution/recovery** (dd/mm/yyyy):
7. **Description of Reaction/Event/ Problem or Product Use Error:**

8. **Relevant tests / laboratory data with date, if available**

9. **Relevant Medical History (e.g. allergies, race, pregnancy, smoking, alcohal use, hepatic/renal dysfunction etc.)**

10. **Seriousness of the reaction (if applicable) :**
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization (Initial or Prolonged)
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (Specify)

11. **Outcome:**
- ☐ Recovered
- ☐ Recovering
- ☐ Not Recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. Suspected Drug

12. **Details of Suspected Drug**

S. No	Name of medicine (Brand/generic)	Batch No.	Expiry Date	Dose taken	Route of administration	Frequency (OD/BD etc.)	Therapy dates		Causality assessment
							Date Started	Date Stopped	
i									
ii									

13. **Action Taken (Please tick)**

	Drug Withdrawn	Dose Increased	Dose Reduced	Dose not Changed	Unknown	NA
i						
ii						

14. **Reaction appeared/disappeared after re-use/stop/reduced dose (Specify details)**

15 **Concomitant Medication including self – medication and herbal remedies (Other medication taken during therapy dates of suspected drug)**

S. No	Name of medicine (Brand/generic)	Dose taken	Route of administration	Frequency (OD/BD etc.	Therapy dates		Indication
					Date Started	Date Stopped	
i							
ii							

D. Reporter Details

Name:
Occupation:
Contact No.:
E-mail:
Address:
Signature & Date :

Additional Information:

- Information provided in this form is handled in strict confidence.
- Submission of a report does not constitute an admission that medical personnel or manufacturer of the product caused or contributed to the reaction.

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ADVICE ABOUT REPORTING

What to report:

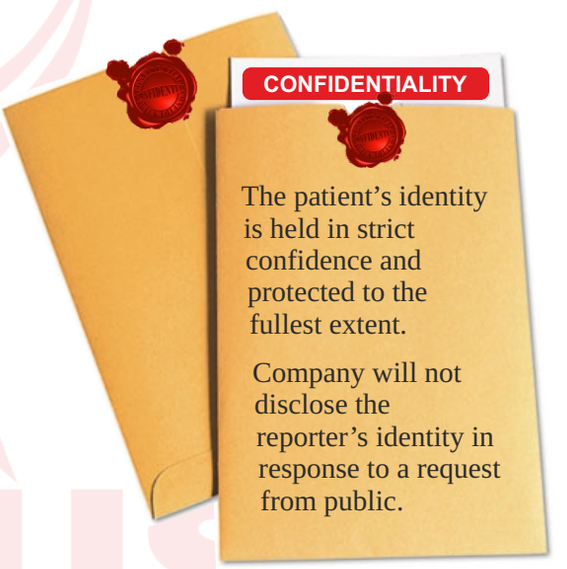
- Serious Adverse Event. An event becomes serious when it results in:
  - Death
  - Life Threatening
  - Hospitalization (Initial or Prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
  - Medically significant
- Non-serious, known/unknown, frequent or rare adverse drug reactions

Who Can Report

- Any health-care professional
  - Doctors / Clinicians / Dentists
  - Pharmacists
- Non health-care professional
  - Patient
  - Relative / Friend / etc.

Report Even, If :

- You are not certain the product caused adverse reaction / event.
- You don't have all the details.



What happens to the submitted information

Based upon the information submitted in this report, data is generated which helps in continuous assesment of benefit – risk ratio of medicines and strengthens the activities related to quality, safety and efficacy of medicinal products.

Where to report ?

After filling, please return this form
to the representative of Venus Remedies Ltd.
or
Send scanned copy of filled form to :
pharmacovigilance@venusremedies.com

Else, send it to :
VENUS REMEDIES LIMITED
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Direct No. : +91-172 - 393-3181, 393-3182, Fax : +91-172 - 2565566

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