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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Scott-Edil **28/6, Industrial Area, Phase-2** **Chandigarh, 160002-INDIA** **www.scott-edil.com**	**Direct No.:** +91-172-5151200 **E.Mail:** pharmacovigilance@scott-edil.com **Help Line:** +91-172-5151200
Report Type (*Please tick*) - Initial Case - Follow-up Case	**FOR SCOTT-EDIL USE ONLY:** **Report No.:** **Date:**

A. PATIENT INFORMATION

1. Patient Initials:	**2.** Age or date of birth:
3. Gender:	**4.** Weight (in Kg.)

12. Relevant investigations(Tests/Laboratory) Data with dates (if available):

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction Start Date	
6. Event / Reaction Stop Date	

7. Describe Event/Reaction/Problem with details, if any

14. Seriousness of the reaction: *(please tick)*

- No - *Yes*
- Death (Date):
- Congenital-anomaly - Life threatening
- Disability
- Hospitalization-Initial/Prolonged
- Other Medically important

15. Outcome:

- Recovered - Recovering
- Not Recovered - Fatal
- Recovered with sequelae - Unknown

C. SUSPECTED MEDICATION(S)

8. Details of Suspected Drug

S. No.	Name of medicine (Brand/ Generic)	Manufacturer (if known)	Batch No.	Expiry Date	Dose	Route	Frequency (OD, BD,etc.)	Therapy Dates		Indication	Casualty Assessment
								Date Started	Date Stopped		
i											
ii											

9. Action taken after reaction (*please tick*)

10. Reaction reappeared/disappeared after reuse/stop/reduced (*please Specify*)

S. No.	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
ii							

Additional Information :

D. REPORTER DETAILS

16. Name & Address :

Pin:
Email:
Contact No:
Occupation:
Signature :

17. Date of this report:

Signature and Name of Receiving Personnel :

- Information provided in this form is handled in strict confidence and protected to fullest extent
- Submission of a report does not constitute an admission that medical personal or manufacturer of the product caused or contributed to the reaction
- Submission of ADR report does not have any legal implication on the reporter.
- The information provided in this form will be forwarded to pharmacovigilance team at Scott-Edil

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WHAT IS ADR?

According to the World Health Organization (WHO), an Adverse Drug Reaction (ADR) is defined as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man **for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."**

WHAT TO REPORT?

You should report any of the following events or issues related to Scott-Edil drug products:

Adverse Events (AE) or Side Effects: Any adverse event or side effect experienced after taking a Scott-Edil drug product.

Misuse or Abuse: Overdosing, abuse, misuse, or off-label use of a drug.

Special Population Issues: Use during pregnancy, breastfeeding, or lactation, with or without adverse effects.

Medication Errors: Any medication errors involving Scott-Edil drug products, with or without adverse effects.

Product Quality Issues: Complaints related to the quality of Scott-Edil drug products, such as damage, discoloration, misshaping, tampering, etc.

Drug Interactions: Adverse reactions due to drug interactions involving Scott-Edil drug products.

Occupational Exposure: Issues related to occupational exposure to Scott-Edil drug products.

WHO CAN REPORT AN ADR/AE?

Healthcare Professionals: Including doctors, clinicians, dentists, pharmacists, nurses, etc.

Non-Healthcare Professionals: Such as patients, relatives, or friends who have sufficient knowledge about the adverse event.

HOW TO REPORT ADR/AE?

Download the Printable PDF of Scott-Edil Suspected ADR Reporting Form, fill-up its print copy and post it to the following address or you can email us the scan copy of form:

DEPARTMENT OF PHARMACOVIGILANCE

Scott-Edil

Corporate Office: 28/6, Industrial Area,

Phase-2, Chandigarh-160002, India

EMAIL ID FOR REPORTING OF ADR/AE

pharmacovigilance@scott-edil.com

HELPLINENUMBER

+91-172-5151200 (9:30AM to 5PM, Monday-Friday)

WHAT HAPPENS TO THE SUBMITTED INFORMATION?

Based upon the information submitted in this ADR form, data is generated which help in continuous assessment of benefit-risk of medicines and strengthen the activities related to quality, safety and efficacy of medicinal product.

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