SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

PHARMACOVIGILANCE CELL

MICRO LABS LIMITED

31, Race Course Road, Bangalore- 560001
Phone No : 080-22343023
E-mail : drugsafety@microlabs.in
Website : www.microlabsltd.com

For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals

MICRO LABS LIMITED

Report No:

A. PATIENT INFORMATION

1. Patient Initials: ……	2. Age…….yrs or…….months Date of Birth: DD / MM / YYYY	3. Sex ☐ M ☐ F	4. Weight ……Kgs

B. Suspected Adverse Reaction

5. Date of reaction started (dd/mm/yy):

6. Date of recovery (dd/mm/yy):

7. Describe reaction or problem

12. Relevant tests / laboratory data with dates

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

14. Seriousness of the reaction

☐ Death (dd/mm/yy)_____ ☐ Congenital anomaly
☐ Life threatening ☐ Required intervention to prevent permanent impairment/damage
☐ Hospitalization-initial or prolonged
☐ Disability ☐ Other (specify)_____

15. Outcomes

☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)

C. Suspected Medication(s)

Sl. No	8. Name (brand and/ or generic name)	Manufacturer (If Known)	Batch No./ Lot No.	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										

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										

11. Concomitant medical products and therapy dates including selfmedication and herbal remedies (exclude those used to treat reaction)

D. Reporter (see confidentiality section overleaf)

16. Name and Professional Address:

Pin code:_____ E-mail:_____

Cell No. / Tel. No. with STD Code: _____

Occupation_____ Signature

17. Causality Assessment	18. Date of this report (dd/mm/yy)

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:**
  - After completing, please return this form to Micro Labs Ltd, Pharmacovigilance Cell
- **What happens to the submitted information:**
  - Information provided in this form is handled in strict confidence. PV cell at Micro Labs will carry out causality analysis and the data is statistically analysed and finally submitted to CDSCO.

Please return this form to:

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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.