SOP No. MUM/CPC/02/2011/R03
FORMAT No. MUM/CPC/002/R00

ADVERSE EVENT REPORTING FORM
(In Confidence)

ipca

A. PATIENT INFORMATION

1. Patient Initials : ☐☐☐
2. Country : _____

3. Sex : ☐ M ☐ F
4. Age at time of event : ☐☐ year
5. Date of Birth: ☐☐☐☐☐☐☐☐ (dd/mm/yyyy)

6. Weight : ☐☐☐ Kg
7. Height : ☐☐☐ cm

B. ADVERSE EVENT

1. Do you consider the adverse event to be serious? ☐ Yes ☐ No
2. If yes, please indicate why the adverse event is considered to be serious : (Check all that apply)

   Death ☐☐☐☐☐☐☐☐ (dd/mm/yyyy) ☐ Disability or Permanent damage ☐ Life-threatening ☐ Congenital anomaly / birth defect

   ☐ Hospitalization - initialor prolonged ☐ Other important medical events ☐ Required intervention to prevent permanent impairment / damage

   If patient died, cause of death and post mortem findings: _____

   _____

   _____

   (Please attach autopsy findings and hospital discharge summaries as required)
3. If the adverse event is not serious, indicate intensity of the adverse reaction : ☐ Mild ☐ Moderate ☐ Severe
4. Date of onset of event: ☐☐☐☐☐☐☐☐ (dd/mm/yyyy) 5. If event stopped, date: ☐☐☐☐☐☐☐☐ (dd/mm/yyyy)

   Time (if available) ☐☐ : ☐☐ (hh/mm) Time (if available) ☐☐ : ☐☐ (hh/mm)
6. Describe event: (Full description of reaction(s), including body site and severity as well as description of signs and symptoms. Whenever possible, describe a specific diagnosis for the reaction)

   _____

   _____

   _____
7. Information on recovery and any sequelae: Recovered ☐ Recovering ☐ Continuing ☐

   Other: _____

   _____
8. Setting where event occurred:

   Hospital ☐ Out-Patient ☐ Home ☐ Nursing Home ☐
9. Relevant tests / laboratory data, including dates:

   _____

   _____

   _____
10. Other relevant history, including preexisting medical conditions: (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic / renal dysfunction, etc.

    _____

    _____
11. Treatment of adverse event :

    _____

    _____

C. SUSPECT MEDICATION(S)

1. Generic Name	2. Brand Name	3. Dosage form & labeled strength	4. Lot No./Brtch No.	5. Expiry Date	6. Manufacturer
# 1					
# 2					

7. Daily Dose (Specify units - mg, ml, mg/kg)	8. Frequency	9. Route of administration	10. Indication for use of suspected drug	11. Therapy dates (if unknown, give duration) Start / End
# 1				(dd/mm/yyyy) (dd/mm/yyyy) Therapy duration: _____ (days)
# 2				(dd/mm/yyyy) (dd/mm/yyyy) Therapy duration: _____ (days)

12. Event abated after use stopped or dose reduced :			13. Event reappeared after reintroduction :		
#1 Yes ☐	No ☐	Not applicable ☐	Yes ☐	No ☐	Not applicable ☐
#2 Yes ☐	No ☐	Not applicable ☐	Yes ☐	No ☐	Not applicable ☐

14. Relationship of the adverse event with the drug: (Please tick in appropriate box)

Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassified ☐ Unclassifiable ☐

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

Generic name	Dosage form and Labeled strength	Daily dose (Specify units- e.g. mg, ml, mg/kg)	Route of administration	Indication for use of the drug	Starting date	Stopping date
# 1					(dd/mm/yyyy)	(dd/mm/yyyy)
# 2					(dd/mm/yyyy)	(dd/mm/yyyy)
# 3					(dd/mm/yyyy)	(dd/mm/yyyy)

D. CLINICIAN (if not reporter)

1. Name and professional address: _____

_____

_____ Pin Code: _____

Tel. No. (With STD Code) _____ Speciality _____

E. REPORTER

1. Name and address _____

_____

_____

Tel. No. (With STD Code) _____

2. Date of this Report ☐☐☐☐☐☐☐☐ (dd/mm/yyyy) 3. Health professional? Yes ☐ No ☐ 4. Occupation _____

5. Also rported to : Regulatory authority ☐ Distributor ☐ No one else ☐ 6. Report Type : Initilal ☐ Follow-up ☐

Signature _____

Please send this form to:

Corporate Pharmacovigilance Cell
Ipca Laboratories Ltd.
142-AB, Kandivli Industrial Estate
Kandivli (West), Mumbai 400 067, India
T: +91 22 6647 4630
F: +91 22 2868 6954 / 2868 2875
E: pharmacovigilance.mumbai@ipca.com

TO BE FILLED BY THE MANUFACTURER

1. Date received by manufacturer : ☐☐☐☐☐☐☐☐ (dd/mm/yyyy)
2. AER No. _____
3. Report source : Study ☐ Literature ☐ Consumer ☐ Health professional ☐
   Distributor ☐ Company representative ☐
   Other _____

Name of the receiver _____ Signature of the receiver _____