



# ADVERSE EVENT REPORTING FORM

Report Date: \_\_\_\_\_

Company Reference No. \_\_\_\_\_

## Patient information

Patient Initials

Age at time of event:

Date of Birth: (dd/mm/yyyy)

Country:

Sex:  M  F

Adverse Event

Product complaint

Weight: (Kg)

Both

## Adverse Event

Is the adverse event serious? Yes  No

If yes, please indicate why it is serious? (Check all that apply)

Death (dd/mm/yyyy) \_\_\_\_\_  Disability  Life threatening  Congenital anomaly/birth defect  
 Hospitalization  Other important medical events

If patient died, cause of the event:

If the adverse event is not serious, indicate the intensity of the adverse reaction: Mild  Moderate  Severe

Date of onset of the event:  If the event stopped, date:

Time (if available)  :  Time (if available)  :

Describe event or product complaint

Outcome/Information on recovery and any sequelae: Recovered  Recovering  Recovered with sequelae

Other: \_\_\_\_\_ Not recovered  Fatal  Unknown

Setting where the event occurred:

Hospital  Out patient  Home  Nursing Home

Relevant tests/ laboratory data (with dates):

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

Treatment of adverse event

Suspected Medication(s) (including indication, therapy dates, action taken)

Lot No. & Expiry date

Event abated after use stopped or dose reduced: Yes  No  Not applicable

Event reappeared after reintroduction: Yes  No  Not applicable

Relationship of the adverse event with the drug: Related  Not related

Concomitant Medication (s) excluding treatment of reaction (name, dose, frequency, route and therapy dates)

**Reporter:**

Name and address: \_\_\_\_\_

\_\_\_\_\_

Tel No: \_\_\_\_\_ E-mail ID: \_\_\_\_\_

Healthcare professional? Yes  No  Occupation: \_\_\_\_\_

Signature & date: \_\_\_\_\_

**Please send this form to:** Corporate Pharmacovigilance Department, Akums Drugs & Pharmaceuticals Ltd., # 304, Mohan Place, Local Shopping Complex, Block - C, Saraswati Vihar, New Delhi - 110034, India

**Tel :** +91-11-47511000

**Fax:** +91-11-27023256

**Email id:** [pv@akums.net](mailto:pv@akums.net)

**If any additional data, then please attach with this form.**