

Cadila Healthcare Limited



Adverse Event Reporting Form

A. Patient Details

Patient Initials: ___ ___ ___	Age: ___ yrs or ___ months	Weight: ___ Kg or ___ Lb	Country: _____
Sex [] F [] M	Date of Birth: <u>DD / MM / YYYY</u>	Pregnant: [] Yes [] No	Tel No: _____

Patient Medical History: _____

B. Adverse event Details

AE term(s): _____	Onset date: <u>DD / MM / YYYY</u>
Description of adverse events: (including sign and symptoms with specific diagnosis, treatment and action taken):	[] Serious [] Non-serious
	[] Patient Died
	[] Involved or prolonged inpatient hospitalization
	[] Life Threatening
	[] Involved persistent or significant disability or incapacity
	[] Congenital anomaly
	[] Medically Significant & other medically important condition

Reporter's Causality: [] certainly [] probably [] possibly [] unlikely [] conditional [] unassessable [] not related

Outcome of the event: [] Recovered [] Recovering [] Not Recovered [] Recovered with sequelae [] Fatal [] Unknown

Lab test Details (with dates, results and normal range)

C. Drug details

Name of the drug:	Strength:	Indication:
Route of Admin:	Dosage form:	Dose:
	Frequency:	Exp date: <u>DD / MM / YYYY</u>
Drug discontinued? Y/N	Start date: <u>DD / MM / YYYY</u>	Stop date: <u>DD / MM / YYYY</u>
		Batch number:

Additional suspect drug (if any) details as above:

Concomitant medications (provide with details):

D. Reporter Details

Name	Occupation: [] Physician [] Pharmacist [] Nurse
Address:	[] Consumer [] Other, specify:
Tel No:	Country: _____
	Also reported to: [] Regulatory Authority [] Distributor [] None
Email:	Date : <u>DD / MM / YYYY</u> , Signature: _____

Send this report to:

To be filled by Manufacturer

Global Pharmacovigilance Cell International Regulatory Affairs dept, Zydus Cadila, PTC, Sarkej-Bavla N.H No 8A, Moraiya, Tal: Sanand. Dist: Ahmedabad – 382210, India Fax: +91-2717-666620 Phone: +91-2717-666327 Email: drugsafety@zyduscadila.com	Date received by receiver: <u>DD / MM / YYYY</u> Name and sign of receiver: Safety Report ID: Report Type: [] Initial [] Follow up, number:
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“A vigilant today for safe tomorrow”