



Intas Biopharmaceuticals Ltd.
Adverse Drug Reaction Reporting Form

Report Type:	Initial <input type="checkbox"/>	Follow-Up <input type="checkbox"/>	Final <input type="checkbox"/>
Patient initials: ___ ___ ___		Country:	

Brand Name	Batch No (If Known)	Exp. Date (If Known)
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PARTICULARS OF PATIENT

Patient Initials ___ ___ ___	Age: _____ Yrs	Sex: <input type="checkbox"/> M <input type="checkbox"/> F *Pregnant <input type="checkbox"/> Y <input type="checkbox"/> N	Weight: _____ kg
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ADVERSE DRUG REACTIONS

1. Reaction Detail

Date Reaction Started _____ / _____ / _____ DD/MMM/YYYY	Date Reaction Stopped _____ / _____ / _____ DD/MMM/YYYY
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2. Patient's Medical History:

3. Diagnosis :

4. Description of Event :

5. Was the ADR Serious?: **Y** **N**

<input type="checkbox"/> Death <input type="checkbox"/> Life threatening	<input type="checkbox"/> Hospitalization –Initial or prolonged <input type="checkbox"/> Congenital abnormality	<input type="checkbox"/> Disability <input type="checkbox"/> Other (Specify) _____
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6. Outcomes of ADR:

<input type="checkbox"/> Resolved(No Sequelae)	<input type="checkbox"/> Lost to Follow -up
<input type="checkbox"/> Resolved (With Sequelae)	<input type="checkbox"/> Death Date: _____
<input type="checkbox"/> Ongoing	Autopsy planned/done <input type="checkbox"/> Y <input type="checkbox"/> N
<input type="checkbox"/> Unknown	Autopsy report Available <input type="checkbox"/> Y <input type="checkbox"/> N

SUSPECTED MEDICATION (S)

Drug Name(s)	Generic Name	Total Daily Dose	Route	Start Date (DD/MMM/YY)	Stop date (DD/MMM/YY)	Indication (if applicable)

CONCOMITANT MEDICATION(s) (including self medication & herbal remedies; exclude those used to treat reaction)
Use additional sheet if required

Drug Name(s)	Generic Name	Total Daily Dose	Route	Start Date (DD/MMM/YY)	Stop date (DD/MMM/YY)	Indication (if applicable)



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Action taken to treat ADR	<input type="checkbox"/> None <input type="checkbox"/> Drug Stopped <input type="checkbox"/> Dose reduced <input type="checkbox"/> Drug Therapy interrupted
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Does reaction abate after stopping drug?	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>	Unknown <input type="checkbox"/>
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Does reaction reappear after reintroduction?	Y <input type="checkbox"/>	N <input type="checkbox"/>	NA <input type="checkbox"/>	Unknown <input type="checkbox"/>
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RELEVANT MEDICAL HISTORY including pre-existing medical conditions:
(e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

Condition	Onset (DD/MM/YYYY)	Details	Present (Y/N)

LABORATORY TESTS UNDERTAKEN

Name of tests	Date	Results

INVESTIGATOR DETAILS

Name of Investigator	Address:	
Investigator Signature		
Name/Position of Reporter (If different from above)	Tel No.	Fax No
Signature of Reporter (If different from above)	Date of report: (DD/MM/YY)	

SPONSOR DETAILS

Name & Address	Intas Biopharmaceuticals Limited Ltd. Plot No. 423/P/A/GIDC, Moraiya Sarkhej - Bavla Highway Tal: Sanand Ahmedabad – 382210 GUJARAT
Tel:	0091 - 2717 – 660100 / 101
Fax:	0091 - 2717 - 251189



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ADDITIONAL INFORMATION (Include medical assessment report e.g. lab tests ECG, etc)