SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For

(Intas Drug Product Name) _____

A. Patient

1. Patient Initials	2. Age at the time of event or Date of birth:	3. Sex: M ☐ F ☐
		4. Body-Weight: _____ Kg

12. Relevant tests / laboratory data with dates

B. Suspected Adverse Reaction

5. Reaction started on Date:

6. Date of recovery:

7. Describe reaction or problem :

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

If the patient is a female, whether pregnant?
Yes ☐ / No ☐ If 'Yes',
Date of last menstrual period: _____
Expected date of delivery: _____

14. Seriousness of the reaction

☐ Death (dd/mm/yyyy) ☐ Congenital anomaly
☐ Life - threatening ☐ Persistent or significant disability or incapacity
Hospitalization -initial or prolonged
☐ Required intervention to prevent permanent impairment / damage
☐ Other (specify):

15. Outcomes

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

C. Suspected Medication (s)

Sr. No.	8. Name (brand and / or generic name)	Manufa-cturer (if known)	Batch No. / Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known, give duration)		Reason for use or prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										

Action taken with suspected drug
Dose reduced ☐ Drug discontinued ☐ Continued in same dose ☐

Sr. 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.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (excluding those used to treat reaction):	D. Reporter
	16. Name and professional address:
	PIN Code : E-mail:
	Tel. No. (with STD code):
	Occupation _____Signature_____
	17. Causality Assessment / 18. Date of this report

NOTE: PLEASE DO NOT LEAVE ANY FIELD BLANK. STRIKE OUT WHERE INFORMATION IS 'NOT AVAILABLE' OR 'NOT APPLICABLE'

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. The pharmacovigilance staff at INTAS 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.**

Note: Fill-up the print copy of the form as completely as possible and send by post to the following

Address: PV Cell, Medical Services Dept., INTAS Pharmaceuticals Limited, Corporate House, Opposite Sola Bridge, Off S. G. Highway, Thaltej, Ahmedabad – 380 054. Gujarat. India.