SUSPECTED DRUG ADVERSE EVENT (SIDE EFFECT) REPORTING FORM

Name of Suspected INTAS Drug Product*: _____

Nature of Event [Tick (√) the box(es) as applicable]:

☐ Adverse event (Side effect) ☐ Lack of drug efficacy ☐ Drug overdose ☐ Drug misuse

☐ Unintended use while being pregnant / lactating / breastfeeding

☐ Other; if 'Other', please specify: _____

Patient Details*:

Name or Initials: _____ Sex: ☐ Male / Female ☐ Age: _____ (Year) _____ (Month)

/ Age Group: Neonate ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Elderly ☐

Weight: _____ kg Height:_____ cm Date of Birth:_____ Hospital Ref. No.:

_____

If Female, is the Patient Pregnant? Yes ☐ / No ☐

If 'Yes', Date of Last Menstrual Period: _____ Expected Delivery Date: _____

Description of the Event*:

Sr. No.	Event	Date Started	Date Stopped	Whether Ongoing: Yes /No

Present Status / Outcome (on this day of reporting)*:

Completely recovered ☐ / Recovering ☐ / Ongoing ☐ / Death ☐ / Unknown ☐ / Other ☐

If 'Other', specify _____

Suspected INTAS Drug Details*:

Drug Name, Strength, Pharmaceutical Form	Brand Name	Condition / Symptom for which It was Given	Details of Dosing	Route of Administration

Additional Relevant Information, If Known:

Any Other Disease or Allergy: Yes ☐ / ☐ No

If 'Yes', please specify: _____

Reporter Details:

Full Name*: _____ Address: _____

Country*: _____ E-mail Address / Tel. No.*: _____

_____

(* Mandatory fields)

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.