ONTOP PHARMACEUTICALS PVT. LTD.

# SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals


**Regulatory Department**
**Ontop Pharmaceuticals Private Limited**
9-D, Bommasandra Jigani Link Rd, Bommasandra Industrial Area,
Bengaluru, Bommasandra, Karnataka 560099 , India
Email: ontoppharma@ontoppharma.com | Contact- 080 2960 3775 (Monday to Saturday between 8.30 am to 5.00 pm, except on public holidays.)


**FOR ONTOP USE ONLY**

Report No.:

Report Type: ❑ Initial ❑ Follow up

12. Relevant tests/laboratory data with dates-

## A. PATIENT INFORMATION

1. Patient Initials - _____

2. Age at time of Event or Date of Birth - _____

3. M ❑ F ❑ Other ❑

4. Weight _____ Kgs

4. a) Height _____ Cm

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.) -

## B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy) -

6. Event/Reaction stop date (dd/mm/yyyy) -

6 (A). Onset Lag Time -

7. Describe Event/Reaction with treatment details, if any-

14. Seriousness of the reaction:No ❑ if Yes ❑ (please tick anyone)

| | |
|---|---|
| ❑Death (dd/mm/yyyy) | ❑Congenital anomaly |
| ❑Life threatening | ❑Disability |
| ❑Hospitalization/Prolonged | ❑Other Medically important |

15. Outcomes

| | |
|---|---|
| ❑Recovered | ❑Fatal |
| ❑ Recovering | ❑ Recovered with sequelae |
| ❑ Not recovered | ❑ Unknown |

## C. SUSPECTED MEDICATION(S)

| S.No | 8. Name (Brand/Generic) | Manufacturer (if known) | Batch No. / Lot No. | Exp. Date (if known) | Dose used | Route used | Frequency (OD, BD etc.) | Therapy | | Indication | Causality Assessment |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Date Started | Date stopped | | |
| i | | | | | | | | | | | |
| ii | | | | | | | | | | | |
| iii | | | | | | | | | | | |
| iv* | | | | | | | | | | | |

| S.No as Per C | 9. Action Taken (please tick) | | | | | | 10. Reaction reappeared after reintroduction (please tick) | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | Yes | No | Effect Unknown | Dose (if reintroduced) |
| i | | | | | | | | | | |
| ii | | | | | | | | | | |
| iii | | | | | | | | | | |
| iv | | | | | | | | | | |

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

| S.No | Name (Brand/Generic) | Dose used | Route used | Frequency (OD, BD, etc.) | Therapy dates Indication | | Indication |
|---|---|---|---|---|---|---|---|
| | | | | | Date Started | Date Stopped | |
| i | | | | | | | |
| ii | | | | | | | |
| iii* | | | | | | | |

Additional Information :

## D. REPORTER DETAILS

16.Name and Professional Address:
_____

Pin: _____ E-mail :

Tel. No. (with STD code)

Occupation: _____ Signature: _____

17.Date of this report (dd/mm/yyyy):

Sign. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

*use separate page for more information