Psychocare Health Private Limited
PCHPL Building, D161A, Phase 7, Industrial Area | Sector 73, Sahibzada Ajit Singh Nagar | Punjab 160055, India
Pharmacovigilance: pv@psychocare.biz | Tel: +91 9545577577 | www.psychocare.biz

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of ADRs by Healthcare Professionals
Forward completed forms to: pv@psychocare.biz | PCHPL Building, D161A, Phase 7, Industrial Area
[MAH PV Helpline / Toll-Free: _____] | Form Version: [__]

Initial Case ☐	Follow-up Case ☐	**FOR MAH / PV USE ONLY**

A. PATIENT INFORMATION *

1. Patient Initials:	**2. Age / Date of birth:**
3. Gender: M ☐ F ☐ Other ☐	**4. Weight (in Kg.):**

B. SUSPECTED ADVERSE REACTION *

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

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

7. Describe Event/Reaction management with details, if any:

Reg. No. / IPD No. / OPD No. / CR No.:

MAH Report No.:

Worldwide Unique No.:

12. Relevant investigations with dates:

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.):

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

☐ Death (dd/mm/yyyy): _____ ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/Generic)	Manufacturer (if known)	Batch/Lot No.	Expiry Date	Dose	Route	Frequency	Therapy Date Started	Therapy Date Stopped	Indication	Causality Assessment
i											
ii											
iii											

iv											
v											
vi											

9. Action taken after reaction (please tick)						
S.No (per C)	**Drug withdrawn**	**Dose increased**	**Dose reduced**	**Dose not changed**	**Not applicable**	**Unknown**
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction (please tick)			
Yes	**No**	**Effect unknown**	**Dose (if reintroduced)**

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**	**Route**	**Frequency (OD, BD, etc.)**	**Therapy Date Started**	**Therapy Date Stopped**	**Indication**
i							
ii							
iii							
iv							
v							

Additional Information:

D. REPORTER DETAILS *

16. Name & Address:

_____

_____

Pin: _____ Email: _____

Contact No.: _____

Occupation: _____ Signature: _____

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

Signature & Name of Receiving Personnel:

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

* Mandatory Fields for suspected ADR Reporting Form