Cipla

Adverse Event Form

A. Patient information

1. Patient Initials ☐☐☐

2. Age at time of event: _____ or Date of Birth: ___/___/_____ dd / mm / yyyy

3. Gender: ☐ M ☐ F

4. Weight: _____Kg.

5. Country: _____

B. Adverse Event

6. Date when event started (dd/mm/yyyy):_____/_____/_____

7. Date of recovery (dd/mm/yyyy): _____/_____/_____

8. Describe event:

9. Relationship of event to the suspected medication
☐ Related ☐ Not related

13. Relevant tests/ laboratory data, including dates

14. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking alcohol use, hepatic/renal dysfunction, etc.)

15. Seriousness of the event : Is the event Serious ☐ or Non serious ☐
If Serious, then choose the criteria
☐ Death (dd/mm/yyyy) ____/____/_____
☐ Life threatening
☐ requires inpatient hospitalization or prolongation of hospitalization
☐ Results in persistent or significant disability/incapacity
☐ congenital anomaly/ Birth defect
☐ other medically important condition

16. Outcomes
☐ Fatal ☐ Continuing ☐ Recovering ☐ Recovered ☐ Unknown
☐ Other (specify) _____

C. Suspected medication(s)

Sr. No.	10. Name (brand and / or generic name)	Manufacturer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

11. **Action taken with respect to Suspect Drug**

☐ None ☐ Dose reduction Date of dose reduction : ____/____/____ (dd/mm/yyyy)
☐ Drug temporarily discontinued Date stopped : ____/____/_____ (dd/mm/yyyy) Date re-started : ____/____/____ (dd/mm/yyyy)
☐ Drug permanently discontinued Date stopped : ____/____/_____ (dd/mm/yyyy)
☐ Dose increased Date of dose increased : ____/____/_____ (dd/mm/yyyy)

12. Concomitant medical products and therapy dates including self medication and herbal remedies (exclude those used to treat event

D. Reporter

☐ Healthcare Professional ☐ Consumer ☐ Other

17. Name and Address: _____

Pin code: _____ E-mail: _____

Cell No./Tel. No. with STD Code: _____

Specialty: _____ Signature:

18. Occupation: _____

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