Cipla
Drug Safety Division

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

☐ 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	Date started	Date stopped	Reason for use or pres-cribed for
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)

___/___/_____

E. Consent

20. Permission Given by Reporter to Follow Up ☐ Yes ☐ No

If Report is from a Consumer, Permission Given to Follow Up with HCP? ☐ Yes ☐ No

HCP Contact Details _____

_____

Tel. no.: 18002677779 email ID.: drugsafety@cipla.com