FORMAT OF ADVERSE EVENT REPORTING FORM

Please mail this form to:
Cadila Pharmaceuticals Limited
Corporate Campus | Bhat | Sarkhej Dholka Road
Ahmedabad – 382210 | Gujarat, India.
Ph-+91-2718-251334, Toll free: 18005325326
Or Email at: Safety.cadila.global@cadilapharma.co.in

For reporting of adverse events

A. Patient Information

1. Name or Initials *: _____

2. Age: _____
or
Date of Birth:
_ _/_ _/_ _ _ _
(dd/mm/yyyy)

3. Sex*:
Male
Female
Other

4. Height: _____cm

5. Weight: _____kg

6. Country:

B. Adverse Event

7. Seriousness of the event:

Death
Hospitalization- initial or prolonged
Congenital anomaly
Required intervention to prevent permanent impairment/damage
Disability
Life threatening

8. Date of Event:
____/____/_____
(dd/mm/yyyy)

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

10. Describe event or problem*:

11. Relevant tests/laboratory data (attach memo, if required):

12. Other relevant history, including pre-existing medical conditions (e.g. allergy, pregnancy, smoking and alcohol use, hepatic/renal dysfunction etc.):

C. Suspect Medication

13. Name* (Brand and Generic)^	14. Strength^	15. Manufacturer^
# 1	# 1	# 1
# 2	# 2	# 2
# 3	# 3	# 3

16. Daily Dose	17. Frequency	18. Route Used
# 1	# 1	# 1
# 2	# 2	# 2
# 3	# 3	# 3

19. Therapy dates:

Start Date (dd/mm/yyyy)	End Date (dd/mm/yyyy)	Duration
# 1	# 1	# 1
# 2	# 2	# 2
# 3	# 3	# 3

20. Batch^	21. Expiry Date^	22. Indication
# 1	# 1	# 1
# 2	# 2	# 2
# 3	# 3	# 3

23. Event abated after discontinuation of suspect medication
Yes No NA

24. Event reoccurred after reintroduction of suspect medication
Yes No NA

25. Concomitant medicinal products (name, dose, frequency and route used), and therapy dates (dd/mm/yyyy) (exclude those used for treatment of adverse event):

26. Outcome of the event:

Fatal
Continuing
Recovering
Recovered
Unknown
Other (specify) _____

D. Reporter

27. Name:

28: Address:

29. Country*:

30. Phone:

31. E-mail:

32. Fax:

33. Healthcare Professional:
Yes No

34. Occupation:

35. Also reported to:

Regulatory Agencies
Distributor/sales personnel

Fields marked * are mandatory. ^ = transcribe exactly from product label.

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ADVICE ABOUT VOLUNTARY REPORTING

CONFIDENTIALITY

Any information related to the identities of the reporter and patient will be kept confidential.

- **Report SERIOUS adverse events. An event is serious when the patient outcome is:**
  - Death
  - Life-threatening (real risk of dying)
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment

  Medical events that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed above shall also be considered as serious events.

- **Report even if:**
  - You're not certain the product caused adverse experience
  - You don't have all the details although point nos. 1, 7, 8, 9, 10, 11, 13 & 27 are essentially required

HOW TO REPORT

- Just fill in the sections that apply to your report
- Attach additional pages if needed
- Use a separate form for each patient and event

WHERE TO REPORT

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