QUALITY YOU CAN TRUST

For VOLUNTARY reporting of Adverse Drug Events by health care professionals

Report #
To filled in by Pharmacovigillance centres receiving the form

Adverse Drug Event Reporting Form

A. Patient information

1. Patient identifier initials (First, last)
2. Age at time of event or Date of birth: (dd/mm/yy)
3. Sex ☐F ☐M
4. Weight kgs

B. Suspected Adverse Event

5. Outcomes attributed to adverse event (check all that apply)
☐ death (dd/mm/yy)
☐ life-threatening
☐ hospitalization- initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other:

6. Dates of event starting (dd/mm/yy)

Dates of event stopping (dd/mm/yy)

8. Describe event or problem

9. Relevant tests/laboratory data, including dates

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

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to & will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constiture an admission that medical personnel or manufacturer or the product caused or contributed to the event.**

BLUE CROSS LABORATORIES LTD.
Peninsula Chambers,
Ganpatrao Kadam Marg, Lower Parel,
Mumbai - 400 013

C. Suspect medication(s)

11. Name (Brand and/or generic name)	(Labeled Strength)	(Manufacturer)
#1		
#2		

12. Dose Frequency Route used
#1
#2

13. Therapy dates (if unknown, give duration)
From To
#1 (dd/mm/yy) (dd/mm/yy)
#2

14. Diagnosis for use (separate indications with commas)
#1
#2

15. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ Not Applicable

16. Lot # (if known) Exp. Date (if known)
#1 #1
#2 #2

17. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ Not Applicable
#2 ☐ yes ☐ no ☐ Not Applicable

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

D. Clinician (if not the reporter)

19. Name and Professional Address:
Pin code:
Tel No.: with STD code
Speciality:

E. Reporter (see confidentiality section below)

20. Name & Address:
Phone #

21. Date of this report (dd/mm/yy)

22. Health professional? ☐yes ☐no

23. Occupation

24. Also reported to
☐ no one else
☐ manufacturer
☐ user facility
☐ distributor

25. If you do not want your identity disclosed to the manufacturer, place an "x" in the box. ☐