Check all that apply:
- ☐ Adverse Event
- ☐ Product Problem
- ☐ Both

ADVERSE EXPERIENCE REPORTING FORM

Report Date: _____ **Company Ref No.** _____ **Local Ref No.** _____

Patient Initials _____	**Age at time of Event:** _____ (or) **Date of Birth:** _____	**Sex:** ☐M ☐F **Weight**_____

Date of Event Onset:

Date of Resolution:

Describe Event, Problem or Product Use Error

Relevant tests/ laboratory data (with date)

Other relevant history, including pre-existing medical conditions

Seriousness

- ☐ Death (dd/mm/yy)_____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment/ damage
- ☐ Other (specify)_____

Outcome

- ☐ Fatal ☐ Recovering ☐ Unknown
- ☐ Ongoing ☐ Recovered ☐ Other (specify)_____

Suspect Medications (including indication, therapy dates, action taken)

Lot No. & Expiry date

Reaction abated after use stopped or dose reduced

Yes ☐ No ☐ Does not apply☐

Reaction reappeared after reintroduction

Yes ☐ No ☐ Does not apply☐

Concomitant health products, excluding treatment of reaction

(name, dose, frequency, route and therapy dates)

Reporter's Information:

Name:

Address:

Contact Number:

Email ID:

Occupation _____

Qualifications:

Relationship with patient (*if any*)

_____

Confidential

ADVICE ABOUT REPORTING

- **Report even if:**
  - You're not certain the product caused adverse reaction
  - you don't have all the details

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Company shall not disclose the reporter's identity in response to a request from the public.

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

- **Who can report:**
  - Any health care professional (Doctors, Dentists, Nurses, Pharmacists, etc)
  - Non healthcare professional (Patient, relative, friend, etc)

Did you know?

Adverse drug reactions are the 4th - 6th leading causes of death

Your 5 minutes could help in ensuring Safer Medicines

What happens to the submitted information?

The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

Pharmacovigilance can only be effective through the active participation of practitioners!!

Where to report:

After completing, please return this form to the representative of Sun Pharma

Else, you may contact:
Global Pharmacovigilance Department
Sun Pharmaceutical Industries Ltd.
Address: SUN HOUSE,
CTS No. 201 B/1,
Western Express Highway,
Goregaon (E),
Mumbai 400063, India
Telephone No. (+91 22) 4324 4324
Fax No. (+91 22) 4324 4343/ +91-22-66455699