



Symbol of Quality Pharmaceuticals

FOR OFFICE USE ONLY

Company Recipient Name: _____

PV Recipient Name: _____

Date Received: _____

PV Reference No: _____

SUSPECTED ADVERSE DRUG EVENT REPORTING FORM

This form is for voluntary/ spontaneous reporting of adverse drug reactions of products marketed by Bosch Pharmaceuticals (Pvt) Ltd.

A. PATIENT INFORMATION

1. Patient Name*: _____ 2. Patient identification Number (If any): _____
3. Sex: Male/ Female 4. If female, Pregnant: Yes / No (Trimester) 5. Age (years): _____ 6. Weight (kgs): _____
7. Allergies (if any): _____ 8. Liver/Kidney Dysfunction (If yes, extent): _____

B. PRODUCT INFORMATION

Name of the product and strength*	Route	Therapy Dates (from/to)	Dose	Indication	Batch No

1. Did reaction stopped after stopping/ changing the dose: Yes/ No (If dose changed, please specify dose: _____)
2. Did the reaction reappear after drug was reintroduced: Yes/ No 3. Product available for evaluation*: Yes/ No

C. EVENT INFORMATION

1. Date of Onset: _____
2. Describe the event with relevant lab tests or any data known*+
3. You consider the problem related to which of the following:
 Adverse Event/Reaction
 Quality Problem
 Medication Error
 Others (please specify) _____
4. Outcome:
 Fatal Unknown
 Recovered Other: _____
 Recovering _____
5. Do you consider this event serious: Yes / No
 If yes please indicate why? Patient died due to reaction Life threatening
 Caused disability/incapacity Involved / prolonged inpatient hospitalization

D. OTHER DRUG(S)/ ALTERNATIVE MEDICINE (S) AND HISTORY

1. Concomitant Drugs used (if any) (exclude those used to treat reaction)*
2. Other Relevant History (diagnostics, lab tests, etc, etc)*

E. REPORTER INFORMATION*

1. Reporter's Name: _____ 2. Affiliation: _____
3. Contact Details: _____ 4. Mailing address: _____
4. Profession: Physician Pharmacist Nurse Patient Other
5. Date Reported: _____ 6. Signature: _____

Send signed filled form at ade@bosch-pharma.com or Pharmacovigilance department, Bosch House, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan

*Compulsary Information

*Additional pages can be used if required

"This form neither has legal value nor can it be presented before any court"