Yellow Card

Suspected Adverse Event Reporting Form

Identities of reporter, patient, institution, and product trade name(s) will remain confidential

A. FOR OFFICE USE ONLY

AE report number_____ Date received_____

B. PATIENT INFORMATION

Name/Initial :
Address :
Contact number :

*Age----- Weight(Kg)------*Gender ☐Male ☐Female ☐Other

Pregnant : ☐Yes ☐No ☐Unknown ☐ Not applicable

C. SUSPECTED ADVERSE EVENT INFORMATION

***Type of event**

- ☐ Adverse drug reaction
- ☐ Product quality problem
- ☐ Medication error
- ☐ Others(Please specify)

Suspected product

Brand/Trade name_____ *Generic name with strength _____

*Indication _____

*Medication Start Date_____ End Date _____

Dosage Form_____ *Frequency (Daily Dose)_____

Batch/Lot number_____ Manufacturer_____

***Describe event including relevant tests and laboratory results:**

***Event start Date**_____

***Event stopped Date**_____

Was the adverse event treated? ☐ Yes ☐ No

If yes, please specify

Action taken after reaction:

- ☐ Dose stopped
- ☐ Dose reduced
- ☐ No action taken

Did reaction subside after stopping / reducing the dose of the suspected product?

☐ Yes ☐ No ☐ Not applicable

Did reaction appear after reintroducing the suspected product?

☐ Yes ☐ No ☐ Not applicable

Seriousness of the adverse event:

- ☐ Not serious
- ☐ Hospitalization or prolongation of hospitalization
- ☐ Disability or permanent damage
- ☐ Congenital anomaly / birth defect
- ☐ Life threatening
- ☐ Death
- ☐ Other Medically important

***Outcomes attributed to the adverse event:**

- ☐ Recovered
- ☐ Recovered/ resolved with specula
- ☐ Not recovered
- ☐ Unknown
- ☐ Fatal (date of death:_____)

Other relevant history : (pre-existing medical history)

☐ Hypersensitivity ☐ Allergies ☐ Liver or kidney problems ☐ Smoking ☐ Alcohol ☐ Diabetes

☐ Others (Please specify) :

D. *OTHER CONCOMITANT MEDICINE INFORMATION

Brand Name	Generic name	Indication	Dosage form	Strength & Frequency

E. *REPORTER INFORMATION

*Name & Address_____

*Email address_____ *Mobile phone_____ *Occupation_____

*Date of this report submission_____ *Signature _____

Evaluation/Review Committee Comments:

ADRM Cell	TSC	ADRAC

*** Mandatory Information** **P.T.O**

General instructions for completing the form :	**What to report :**
• Detailed information about each field can be found in the instructions available in the DGDA website. (www.dgda.gov.bd). • Fill in as much information as possible. Do not leave anything blank. If unknown, write "unknown" or "n/a" if not applicable.	• Serious adverse drug reactions • Unknown or unexpected ADRs • All suspected reactions to new drugs • Unexpected therapeutic effects • All suspected drug interactions • Product quality problems • Treatment failures • Medication errors

How to report :

Suspected and observed drug-related reactions must be reported using the electronic version of the reporting form in a fillable pdf available on the DGDA website (www.dgda.gov.bd).

Also submitted to the ADRM Cell by email (adrmcell.dgda@gmail.com / dgda.gov@gmail.com), post, or fax (+8802 9880854). In emergency cases or when forms are not readily available, reports can also be made to the ADRM cell by phone (+8802 9880803).

Send all completed forms to:

Directorate General of Drug Administration
Aushad Bhavan, Mohakhali, Dhaka-1212, Bangladesh
Tel : 8802 9880803, 9880864, 9880897, 9880924, Fax : 8802 9880854,
E-mail : dgda.gov@gmail.com