Adverse Drug Reaction Reporting form

Confidential Information

The information supplied by you will contribute to the overall improvement of drug safety and therapy

1. Patient information

1.1 **Patient name or Initials**_____

1.2 **Country**_____

1.3 **Date of Birth or Age or Age group of patient:** _____

- ☐ Neonate (0-1month)
- ☐ Infant (1month-1yr)
- ☐ Child (1yr-11yrs)
- ☐ Adolescent (12-17yrs)
- ☐ Adult (18-64yrs)
- ☐ Elderly (above 65yrs)

1.1 **Sex / Gender of patient**

Male☐ **Female ☐**

1.2 **Any known allergy** **☐No** **☐Yes (specify)**_____

1.3 **Pregnancy status** **☐ Pregnant** **☐ Not Applicable** **☐ Not pregnant**

2. Suspected Adverse Reaction (s)/ Side effect (s)

2.1 **Date reaction/side effect started (onset date):**_____

2.2 **Brief description of reaction (s):** _____

3. Any relevant Medical/social History. (eg pre-existing medical conditions e.g. allergies, smoking, alcohol use, hepatic/ renal dysfunction etc)

_____

4. Suspected substance/medicinal product (s)

Medicine/ Product Name	Manufacturer	Batch /Lot no	Route (s) of administration	Daily dose	Start date	Stop date

5. Other medicines currently being used by the patient

Medicine/ Product Name	Manufacturer	Batch /Lot no	Route (s) of administration	Daily dose	Start date	Stop date

6. Past medication history (List all medicines used in the last 3 months including herbals, if pregnant indicate medicines used in the 1st trimester)

Medicine/ Product Name	Manufacturer	Batch /Lot no	Route (s) of administration	Daily dose	Start date	Stop date

7. De-challenge/Re-challenge

7.1 Did the reaction disappear/resolve/reduce after the drug was stopped?

☐ Yes. ☐No ☐Unknown ☐N/A

7.2 Did the reaction reappear after the drug was reintroduced?

☐ Yes. ☐No ☐Unknown ☐N/A

8. Any laboratory investigations/ tests done and Results

☐ Yes. ☐No

9. Grading of the adverse reaction /side effect

9.1 How Severe is the reaction?

☐ Mild

☐ Moderate

☐ Severe

☐ Fatal

☐ Unknown

9.2 Is the reaction serious? ☐Yes ☐No

9.3 If reaction is serious, what is reason for seriousness:

☐ caused Hospitalization/Prolonged Hospitalization

☐ caused Disability

☐ caused Congenital anomality

☐ was/is Life threatening

☐ caused Death

9.4 Action taken with the Suspected substance/medicinal product (s)

☐ Drug withdrawn.

☐ Dose reduced.

☐ Dose increased.

☐ Dose not changed

☐ Not applicable.

☐ Unknown

9.5 Current situation/Outcome:

☐ Recovered.

☐ Recovered with sequelae/a negative health impact.

☐ Recovering

☐ Not recovered

☐ Death.

☐ Unknown

10. Has this Suspected Adverse Reaction (s)/ Side effect (s) been reported to your doctor?

☐Yes ☐No

10.1 If yes, Can the doctor be contacted by Beta Healthcare? ☐Yes ☐No

10.2 If yes, please provide the doctor's contact details:

10.3 Doctors name_____

10.4 Doctors Tel. No._____

10.5 Doctor's Email address:_____

11. Your effort in filling this form is greatly appreciated. Kindly provide your details below.

Reporter Details

11.1 Reporter's name or initials_____

11.2 Telephone No_____

11.3 Email address: _____

11.4 Date: _____

Send completed form to Beta Healthcare Pharmacovigilance division.

Email; drugsafety@ke.aspenpharma.com

Patient's and reporter's identity is held in strict confidence

FOR OFFICIAL (Beta Healthcare) USE ONLY

ADR Report No:_____

Date Received:_____