# FOOD AND DRUGS AUTHORITY

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## ADVERSE REACTION REPORTING FORM

From:..... To:.....

FDA/ADR
FOOD AND DRUGS AUTHORITY
In Strict Confidence

# ADVERSE REACTION REPORTING FORM

**(Please complete all sections as much as possible)**

## (A) PATIENT DETAILS

Age/Date of Birth (dd/mm/yyyy): / / Wt (kg):.....
Gender: M ( ) F ( ) If female, Pregnant Yes ( ) No ( ) Age of Pregnancy:.....
Name/Folder Number:..... Telephone No.:.....
Hospital/Treatment Centre:.....

## (B) DETAILS OF ADVERSE REACTION AND ANY TREATMENT GIVEN

(Attach a separate sheet and all relevant laboratory tests/data where necessary)

Date reaction started (dd/mm/yyyy): / / Date reaction stopped (dd/mm/yyyy): / /

## (C) OUTCOME OF ADVERSE REACTION

Recovered ( ) Not yet recovered ( ) Unknown ( )
Did the adverse reaction result in any untoward medical condition? Yes ( ) No ( ) If yes, Specify.....
**SERIOUSNESS:** Death ( ) Life threatening ( ) Disability ( ) (specify).....
Hospitalization ( ) Others (specify).....

## (D) SUSPECTED PRODUCT(S) (Attach sample or product label if available)

| Brand name | Generic name | Batch number | Expiry date | Manufacturer |
|---|---|---|---|---|
| | | | | |
| **Reasons for use (Indication):** | | **Dosage regimen:** | **No. of days given:** | **Route of administration:** |
| | | | | |
| Date started (dd/mm/yyyy): / / Date stopped (dd/mm/yyyy): / /<br>*Did the adverse reaction subside when the drug was stopped (de-challenge)?* Yes ( ) No ( ) | | | | |
| **Was the product prescribed? Yes ( ) No ( )** | | **Source of drug:** | | |

Was product re-used after detection of adverse reaction (re-challenge)? Yes ( ) No ( )
Did adverse reaction re-appear upon re-use? Yes ( ) No ( )

## (E) CONCOMITANT DRUGS: INCLUDING COMPLEMENTARY MEDICINES, ADMINISTERED AT THE SAME TIME AND/OR 3 MONTHS BEFORE (Attach a separate sheet when necessary)

| Name of Drug | Daily dose | Date started | Date stopped/Ongoing | Reason(s) for use |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

## (F) REPORTER DETAILS

Name of Reporter:..... Profession:.....
Institution's Address:.....
Signature:..... Tel:..... Email:.....
Date (dd/mm/yyyy): / /

***Confidentiality:** Identities of the reporter and the patient will remain strictly confidential**

For all questions relating to Suspected Adverse Reactions, please call the Food and Drugs Authority on

- Landline: +233 (0302) 233 200 / 235 100
- Mobile: +233 (024) 4310 297
- Hotline: +233 (029) 9802 932 / 3
- Toll Free Line: 0800 151 000 (Only for Vodafone and Airtel)
- Fax: +233 (0302) 229 794
- E-mail: drug.safety@fda.gov.gh

Please return the completed form to:
Food and Drugs Authority, P. O. Box CT 2783, Cantonments - Accra, Ghana.

You can report directly or download this form from the Food and Drugs Authority's website:
www.fdaghana.gov.gh

**Please, note that this report does not constitute an admission that the reporting medical professional or the suspected product caused or contributed to the event.**

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**ADVICE ABOUT VOLUNTARY REPORTING**

Report all suspected adverse reactions to regulated products:

- Drugs (allopathic/herbals)
- Vaccines
- Cosmetics
- Medical devices
- Blood and blood products
- Household chemicals

Report on all

- Adverse Reactions
- Lack of Efficacy or Therapeutic Failure/Ineffectiveness
- Suspected Product Defect
- Medication Error
- Suspected Counterfeit

**Report even if:**

*You're not certain the product caused the event
*You don't have all the details

Your support of the Safety Monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of drug safety and therapy in Ghana.

PLEASE USE ADDRESS BELOW - JUST FOLD IN THIRDS AND MAIL

*fold along this line*

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WHEN COMPLETED, PLEASE CALL OR SEND WHATSAPP TO **0244 310 297** FOR PICK UP OR CONTACT THE NEAREST FDA REGIONAL OFFICE OR SEND BY POST TO:

**FOOD AND DRUGS AUTHORITY**
**P. O. BOX CT 2783**
**CANTONMENTS**
**ACCRA, GHANA**

***Confidentiality:** Identities of the reporter and the patient will remain strictly confidential**