FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

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FDA/HPT/SMC/SMD/VGU/22/0184

29th April 2022

Dear Healthcare Professional,

**SAFETY ALERT: - RECALL OF PFIZER's ACCUPRIL (QUINAPRIL HYDROCHLORIDE)**

The Food and Drugs Authority (FDA) wishes to bring to your notice a voluntary recall by Pfizer of five batches of its antihypertensive drug, Accupril (Quinapril Hydrochloride) tablets, due to presence of N-Nitroso Quinapril, a cancer-causing impurity.

Quinapril is indicated for the treatment of hypertension, to lower blood pressure and in the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis.

Although, the FDA has not approved Accupril (Quinapril) tablets for use in Ghana or granted approval for its importation on a named patient basis (this is approval for individual patient use), this information is being brought to your notice to enable you advise your patient who may have been prescribed Accupril from other jurisdictions where they are approved for use.

The recall follows recent testing of the products that indicated that N-nitroso-quinapril was present in these batches above Acceptable Daily Intake (ADI) level.

The affected products are Accupril (Quinapril HCl) tablets of strength 10mg, 20mg and 40mg with batches listed below:

| Batch | Expiration Date | Strength | Package Type |
|---|---|---|---|
| DR9639 | 2023 MAR 31 | 10 mg | 1 x 90 count bottle |
| DX8682 | 2023 MAR 31 | 20 mg | 1 x 90 count bottle |
| DG1188 | 2022 MAY 31 | 20 mg | 1 x 90 count bottle |
| DX6031 | 2023 MAR 31 | 40 mg | 1 x 90 count bottle |
| CK6260 | 2022 MAY 31 | 40 mg | 1 x 90 count bottle |

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

**Advice to patients:**
Patients taking Accupril are not at an immediate risk of developing cancer. The risk however increases with long term exposure to the impurity at levels above the ADI. Patients taking any of the affected batches should contact their healthcare provider for advice.

**Advice to healthcare professionals**:
Healthcare professionals with patients taking these medicines should assess if their products are affected and provide alternatives.

The FDA would also like to advice patients and healthcare professionals to report adverse reactions to all products including **lack of therapeutic effect** and **medication errors** through the following:

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at http://adr.fdaghana.gov.gh/patient.php;
- Call Mobile No. 024 4310 297
- Call Hot line No. 0308250070
- Download and complete the Adverse Drug Reaction (ADR) Form, then submit it at the nearest heath facility

Yours faithfully,

DR. MRS. AKUA O. AMARTEY
DCEO, TECHNICAL OPERATIONS DIVISION
FOR: CHIEF EXECUTIVE OFFICER