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Audience: Healthcare Professionals and Patients

SAFETY ALERT: CONTAMINATION OF LOSARTAN ACTIVE SUBSTANCE WITH MUTAGENIC AZIDO IMPURITIES

The Food and Drugs Authority (FDA) wishes to inform you about information from European health authorities regarding the detection of previously unknown Azido impurity, 4-Chlor-Azidomethyltetrazole in some sartan medicines.

Sartans are prescription-only medicines (POM) used to treat high blood pressure. Some of the Sartan antihypertensives affected include Irbesartan, Losartan Potassium and Valsartan.

The azido impurity is considered a mutagen which may increase the risk of cancer but the specific risk for this azido impurity to cause cancer in humans is unknown.

The FDA in collaboration with Denk Pharma GmbH & Co. KG. is recalling losartan-containing products, namely, Colosar-Denk (Losartan potassium/Hydrochlorothiazide) and Losar-Denk tablets from the Ghanaian market as a precautionary measure due to the presence of 4-Chlor-Azidomethyltetrazole.

This is a precautionary measure to prevent further use, however, there is no evidence that this impurity (4-Chlor-Azidomethyltetrazole) has caused any harm to patients.

It is not clear whether azido impurities are present in other sartan-containing anti-hypertensives marketed in Ghana. This is however, a developing issue and the FDA is working with international regulatory authorities and manufacturers to further understand the potential risk and other impacted products to provide updates as the investigation progresses.

What should patients do?

- Patients **SHOULD NOT STOP** taking their Colosar-Denk, Losar-Denk or other Sartan-containing anti-hypertensive products unless this has been discussed with your health professional. This is because suddenly stopping medication for high blood-pressure can be risky.
- If you have any questions or concerns about this issue, you should speak to your health professional.

What should health professionals do?

- Wholesale pharmacies are to **STOP** supplying Colosar-Denk and Losar-Denk tablets and return these to the supplier.

How to Report Safety problems

The FDA will like to advice patients and healthcare professionals to report side effects of Sartan-containing anti-hypertensives products and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh or call Mobile no: 0244 310 297 or send an email to drug.safety@fdaghana.gov.gh.

Additionally, to report and receive the latest safety alerts and recalls, download the Med Safety App from Google Play or the App Store.

Yours faithfully,

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CHIEF EXECUTIVE OFFICER