



# Food and Drugs Authority

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FDA/SMC/SMD/VGU/18/0398

6<sup>th</sup> December 2018

Dear Healthcare Professional,

## **RECALL OF AMLODIPINE/VALSARTAN COMBINATION TABLETS DUE TO CONTAMINATION WITH AN IMPURITY (N-NITROSO-DIMETHYLAMINE)**

The Food and Drugs Authority (FDA) wishes to inform you that it has initiated the recall of the underlisted Amlodipine/Valsartan Combination Tablets manufactured by Denk-Pharma GmbH & Co. KG due to contamination with an impurity, N-nitrosodimethylamine (NDMA), which is detected above specification limits.

1. Amva Denk 10/160 Tablets (Amlodipine 10mg and valsartan 160mg)
2. Amva Denk 5/160 Tablets (Amlodipine 5mg and valsartan 160mg)
3. Amva Denk 5/80 Tablets (Amlodipine 5mg and valsartan 80mg)

The impurity, which has been classified as a probable human carcinogen is found in active pharmaceutical ingredients (API) manufactured by Zhejiang Huahai Pharmaceuticals in Linhai, China. This chemical is typically found in very small amounts in certain foods, drinking water, air pollution, and certain industrial processes.

The FDA in collaboration with Denk-Pharma GmbH & Co. KG has instituted recall of these products from the Ghanaian market.

Meanwhile, patients and healthcare professionals are to take note of the following information:

### **Information for Patients**

- Do not stop taking your Amlodipine/Valsartan Combination Tablets unless you have been told to do so by your doctor or pharmacist because not all Amlodipine/Valsartan Combination Tablets contains the NDMA.
- Contact your doctor or pharmacist if you are taking products containing Amlodipine/Valsartan Combination Tablets manufactured by Denk-Pharma GmbH & Co. KG.

### **Information for healthcare professionals**

- Stop supplying all Amlodipine/Valsartan Combination Tablets manufactured by Denk-Pharma GmbH & Co. KG and return the medicine to your wholesale supplier

or contact the FDA on Mobile: 024 4310 297 or Email:  
[drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh).

Additionally, healthcare professionals and patients are encouraged to be more vigilant when medicines and other health products and report any untoward events to the National Pharmacovigilance Centre, Food and Drugs Authority through the underlisted means:

- E-mail : [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh)
- Healthcare professionals : <http://adr.fdaghana.gov.gh/>
- Patients : <http://adr.fdaghana.gov.gh/patient.php>
- Telephone : 024 4310 297

The FDA is carrying out further investigations into this issue and any new information will be communicated to you.

Yours faithfully,

Singed

ISABELLA MANSA AGRA (MRS)  
AG. DCE, FOOD INSPECTORATE DIVISION  
FOR: CHIEF EXECUTIVE OFFICER