



Food and Drugs Authority

Head Office
P. O. Box CT 2783,
Cantonments, Accra-Ghana
Tel: (+233-302)233200, 235100
Fax: (+233-302)229794, 225502
Email: fda@fdaghana.govgh

FDA/SMC/SMD/VGU/18/0346

25th September 2018

Dear Healthcare Professional,

UPDATE: SAFETY INFORMATION ON MEDICINES CONTAINING VALSARTAN FROM ZHEJIANG HUAHAI FOLLOWING DETECTION OF AN IMPURITY

This is a follow up to the Food and Drugs Authority's safety alert dated 9th July 2018 (ref. no. FDA/SMC/SMD/VGU/18/0239)¹ relating to the contamination of some medicines containing valsartan manufactured with active ingredient from Zhejiang Huahai Pharmaceuticals in Linhai, China with an impurity, N-nitrosodimethylamine (NDMA), an organic chemical that is in a family of potent cancer causing agents.

Further investigations by the FDA have revealed that medicines containing valsartan manufactured by Actavis Group (now Accord Healthcare), Denk-Pharma GmbH & Co. KG and Torrent Pharmaceuticals Ltd were contaminated with the impurity.

The FDA in collaboration with the importers have instituted a 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 valsartan medicine unless you have been told to do so by your doctor or pharmacist because not all valsartan containing products contains the NDMA.
- Contact your doctor or pharmacist if you are taking products containing valsartan manufactured Actavis Group (now Accord Healthcare), Denk-Pharma GmbH & Co. KG and Torrent Pharmaceuticals Ltd.

Information for healthcare professionals

- Stop supplying all valsartan containing medicines from Actavis Group (now Accord Healthcare), Denk-Pharma GmbH & Co. KG and Torrent Pharmaceuticals Ltd and return these medicines to your wholesale supplier or contact the FDA on Mobile: 024 4310 297 or Email: drug.safety@fdaghana.gov.gh.

¹ <https://fdaghana.gov.gh/images/stories/pdfs/Safety%20Monitoring/2018/GH%20FDA%20Valsartan.pdf>

Additionally, healthcare professionals and patients are encouraged to be more vigilant when medicines and other health products are used 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
- Healthcare professionals : <http://adr.fdaghana.gov.gh/>
- Consumers : <http://adr.fdaghana.gov.gh/patient.php>
- Telephone : 024 4310 297

Please, note that investigations are ongoing and any new information will be communicated to you.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER