

SAFETY ALERT - CONTAMINATED BATCHES OF NORVASC 5MG TABLETS

The Food and Drugs Authority (FDA) is alerting healthcare professionals and the public about a recent incident of contamination of two batches of Norvasc 5mg tablets (**FR3135 and FT2343**) produced by the American Pharmaceutical Company, Viatris Inc.

Norvasc 5mg tablets contains amlodipine besylate as an active ingredient and is used in the management of high blood pressure or angina.

The Taiwan Food and Drug Administration (TFDA) on 7th January 2023 announced an order recalling the two batches of the high blood pressure tablets which have been found to contain iron wires.

The Norvasc 5mg tablets registered in Ghana by the FDA is manufactured by Pfizer Pharmaceuticals LLC, Puerto Rico, and **not** Viatris Inc., USA. The two batches being recalled in Taiwan are therefore not supposed to be commercially available on the Ghanaian market.

As a result, the FDA advises healthcare professionals and the public who may be in possession of these batches of Norvasc 5mg tablets to immediately **stop using** the product and submit remaining stock to the nearest FDA offices nationwide.

The FDA is encouraging healthcare professionals and the general public to report availability of the affected batches on the Ghanaian market to FDA through the hotline 0551112224/5.

You are also requested to report adverse reactions to all products including lack of efficacy, medication error or suspected counterfeit and substandard products to the FDA 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/>
- Download and complete the Adverse Reaction (AR) Reporting Form (<http://www.fdaghana.gov.gh/operational-guide.php>)
- Community Pharmacies Designated as Patient Safety Centres

Details of Norvasc 5mg tablets recalled by TFDA

Product Name: Norvasc 5mg tablets

Product Manufacturer: Viatris Inc.,USA

Batch Number: FR3135 and FT2343

Pictures of the product

