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FDA/HPT/VVC/SMD/VGU/23/0295 29th August 2023

Dear Healthcare Professional,

SAFETY ALERT: RECALL OF AMEDIN® (AMLODIPINE BESILATE 5MG & 10MG) TABLETS

The Food and Drugs Authority (FDA) is writing to inform you about the recall of the underlisted batches of Amlodipine Besilate 5mg & 10mg **(Amedin** 5mg & 10mg) Tablets manufactured by Medreich Limited, Bangalore Unit – III, India from the distributors, wholesalers, pharmacies and hospitals levels.

Product Description	Impacted Batch Number	Manufacturing date	Expiry date
Amedin 10mg Tablets	B10363	01/03/2021	28/02/2024
Amedin 5mg Tablets	B20554	01/04/2022	31/03/2025
Amedin 10mg Tablets	B20555	01/04/2022	31/03/2025

This recall is being carried out due to ongoing stability out-of-specification results reported in the related substance test for any other secondary impurity and the sum of the secondary peak.

Amedin Tablets is a calcium antagonist registered by the FDA for the treatment of hypertension and angina.

Advice to patients:

- Patients taking Amedin 10mg or 5mg of the affected batches should **immediately** return these to the hospital or pharmacy where they obtained it, or to the nearest Food and Drugs Authority Office for safe disposal.

Advice to healthcare professionals:

- Healthcare professionals in hospitals or community pharmacies that have stocked Amedin 10mg or 5mg should verify if they have the affected batches in stock and return them to the source of purchase or any office of the FDA.

- Hospitals and Community Pharmacies who have dispended Amedin should verify the batches dispended and contact affected patients to return the products.

Patients and healthcare professionals may call the FDA on Mobile No: 024 431 0297/ 055 111 2224 or email to drug.safety@fda.gov.gh for enquiries or further guidance.

You are reminded to report adverse reactions to Amedin Tablets and all products including **lack of therapeutic effect medication errors, suspected product quality and substandard or falsified products:**

- 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 reporting form and submit it at the nearest health facility.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER