Medicine Quality Alert: Class II Medicine Recall of Cardipril 5 (Enalapril Maleate) Tablets, Batch No. T24A016

The Pharmacy and Poisons Board has mandated Zain Pharma Limited to initiate an urgent recall of Cardipril 5 (Enalapril Maleate) Tablets, Batch No. T24A016

From: Pharmacy and Poisons Board Date of Recall Initiation: 17th July 2025

Recall Reference Number: REC/2025/023

Recall Classification: Class II Recall Level: Retail/Facility level

Manufacturer: Zain Pharma Limited, Kenya

Product name: Cardipril 5 Tablets

Active Pharmaceutical Ingredient: Enalapril Maleate

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
T24A016	01/2024	12/2026	100's

Brief description of the problem

The product batch is being recalled due to failure to comply with specifications for hardness test, following an investigation into a market complaint regarding powdering/crumbling of the tablets.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batch immediately. Await contact from Zain Pharma Limited to arrange the return.

Action for patients and caregivers

No further action is required by patients as this is a Retail/hospital Pharmacy and Wholesaler/Distributor level recall. You are advised to talk to your healthcare professional if you have the above batch of Cardipril 5 (Enalapril Maleate) tablets.

Further Information

For inquiries about consignments of the impacted batch, please contact Zain Pharma Limited at: info@zainpharma.co.ke or regulatory@zainpharma.co.ke, or by Telephone at: +254 738 017 004

You are advised to promptly report any case(s) of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at *271#
- Email <u>pv@ppb.go.ke</u> or <u>pms@ppb.go.ke</u>
- Telephone No. 0795743049
- Mobile application: mPvERS, both Android and iOS

For any further enquiries and feedback on the product recall, contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at pms@ppb.go.ke