

Medicine Quality Alert: Class II Recall of Enril 5 (Enalapril Maleate USP 5mg) Batch Number KN532

The Pharmacy and Poisons Board has issued a mandatory recall of Enril 5 (Enalapril Maleate USP 5mg), Batch No KN532; due to out-of-specification results.

From: Pharmacy and Poisons Board
Published: 15/11/2023

Recall Reference Number: REC/2023/16

Recall Classification: Class II

Recall Level: Retail/Facility level

Local Technical Representative: Galaxy Pharmaceutical Limited

Manufacturer: Prism Life Sciences Ltd, India

Product name: Enril 5 Tablets

Active Pharmaceutical Ingredient: Enalapril Maleate USP 5mg

Affected Counties: All

Affected batches

Batch Number	Date of Manufacture	Date of expiry	Pack Size
KN532	02/2023	01/2026	30's

Brief description of the problem

Following routine market surveillance activities, the Pharmacy and Poisons Board (PPB) detected out-of-specification (OOS) results for Enril 5 (Enalapril Maleate usp 5mg), Batch no *KN532*.

Action for healthcare professionals

You are advised to stop supplying the above batches and immediately quarantine all remaining stocks. The company, Galaxy Pharmaceutical Limited, will contact healthcare professionals directly to arrange the return of the products.

Action for patients and carers

Patients currently prescribed Enril 5 (Enalapril Maleate usp 5mg), Batch no KN532 should be contacted by their prescribing healthcare professional. The patients should continue taking other batches of the product other than the impacted batches and as prescribed by the healthcare professional.

Further Information

For stock inquiries, please contact Galaxy Pharmaceutical Limited at: info@galaxypharma.co.ke or pvigilance@galaxypharma.co.ke or Tel: +254 3748551/2/3/4

You are advised to promptly report any cases 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 pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the Pharmacy and Poisons Board by email: pms@ppb.go.ke