

# Medicine Quality Alert: Class I Medicine Recall of Flamodip (Amlodipine) 5 Mg Tablets Batch No FLD303

The Pharmacy and Poisons Board has mandated Harleys Limited to initiate an urgent recall of Flamodip (Amlodipine) 5 Mg Tablets Batch No **FLD303** Manufactured By Medico Remedies Pvt Ltd.

From: Pharmacy and Poisons Board  
Published: 26<sup>th</sup> September 2024

**Recall Reference Number:** REC/2024/025

**Recall Classification:** Class I

**Recall Level:** Consumer-level

**Local Technical Representative:** Harleys Limited

**Manufacturer:** Medico Remedies Pvt Ltd, India

**Product name:** Flamodip

**Active Pharmaceutical Ingredient:** Amlodipine 5mg

**Affected counties:** All

## Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
FLD303	10/2023	09/2026	30 Tablets

## Brief description of the problem

The product is being recalled due to wrong product (label and contents are different products). *The label of the secondary package for Flamodip (Amlodipine) 5 Mg Tablets reads Flamodip-5 (Amlodipine) whereas the primary package reads Flaminopril-5 (Enalapril).*

## Action for healthcare professionals

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

## Action for patients and members of the public

Patients and members of the public who are in possession of the product batch are advised to IMMEDIATELY return the product to the nearest healthcare facility.

## Further Information

For inquiries about consignments of the impacted batch, please contact Harleys Limited at: [regulatory@harleysltd.com](mailto:regulatory@harleysltd.com), [info@harleysltd.com](mailto:info@harleysltd.com) or Phone: +254 20 4261000, Mobile: +254 722 202030 | 0773 106 788 | 0737 203030.

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#
- Mobile application: mPvERS both Android & iOS
- Email [pv@ppb.go.ke](mailto:pv@ppb.go.ke) or [pms@ppb.go.ke](mailto:pms@ppb.go.ke)
- Telephone No. 0795743049

For any further enquiries and feedback on the product recall, kindly contact the post-marketing surveillance unit of The Pharmacy and Poisons Board Kenya “the Board” via email at [pms@ppb.go.ke](mailto:pms@ppb.go.ke) and [Recall Feedback Form](#)