Medicine Quality Alert: Class II Recall of Papazyme (Papain, Fungal Diastase, and Simethicone) Tablets, Batch No. P1024042

Micro Labs (EA) Ltd has initiated a voluntary recall of Papazyme (Papain, Fungal Diastase, and Simethicone) Tablets, Batch No. P1024042, manufactured by Gelpach International, India

From: Pharmacy and Poisons Board Date of Recall Initiation: 02/12/2025

Recall Reference Number: REC/2025/036

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

Local Technical Representative: Micro Labs (EA) Ltd

Manufacturer: Gelpach International, India

Product name: Papazyme

Active Pharmaceutical Ingredient: Papain, Fungal Diastase, and

Simethicone

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
P1024042	06/2024	05/2027	2 x 4's

Brief description of the problem

The product is being recalled due to an observed issue of bulging strip packs.

Action for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and await contact from Micro Labs (EA) Limited or Laborex Kenya to arrange the return.

Action for patients and carers

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 Papazyme Tablets.

Further Information

For inquiries about consignments of the impacted batch, please contact Micro Labs (EA) Limited and Laborex Kenya by email at: regulatoryeastafrica@microlabs.africa and ssavla@laborex-healthcare.com or by Telephone at +254 113 213 203, +254 (0) 20 69 39 162 or +254 769 579 060.

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