

Medicine Quality Alert: Class I Medicine Recall of S-Prazo (Esomeprazole Magnesium Delayed-Release Capsules 40mg) Batch No SPZ-404

The Pharmacy and Poisons Board has mandated Harleys Limited to initiate an urgent recall of S-Prazo Batch Number SPZ404.

From: Pharmacy and Poisons Board

Date of Recall Initiation: 24th April 2025

Recall Reference Number: REC/2025/017

Recall Classification: Class I

Recall Level: Consumer-level

Local Technical Representative: Harleys Limited

Manufacturer: Medico Remedies Limited, India

Product name: S-Prazo

Active Pharmaceutical Ingredient: Esomeprazole Magnesium Delayed-Release Capsules 40mg

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
SPZ 404	09/2024	08/2027	30's

Brief description of the problem

The product is being recalled following a market complaint of a product mix-up involving S-Prazo (Esomeprazole 40mg) Batch No. SPZ404, wherein it was detected and confirmed that a strip of Levofloxacin 500mg tablet was found in a pack of Esomeprazole 40mg Capsules.

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 have 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, 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 or pms@ppb.go.ke
- Telephone No. 0795743049

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