Medicine Quality Alert: Class I Medicine Recall of S-PRAZO (Esomeprazole Magnesium Delayed-Release Capsules 40mg) Batch No SPZ-302

Harleys Limited has initiated an urgent voluntary recall of S-PRAZO (Esomeprazole Magnesium Delayed-Release Capsules 40mg) Batch No SPZ-302 Manufactured by Medico Remedies Limited, India.

From: Pharmacy and Poisons Board
Published: 15th August 2024

Recall Reference Number: REC/2024/021
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
SPZ-302	12/2023	11/2026

Brief description of the problem
The product is being recalled due to a market complaint wherein it was reported that there was a mixup with **Donystatin** Tablets blisters within some secondary packets “two different blister strips within one outer carton”.

S-Prazo is a proton pump inhibitor used to treat GERD, reduce the risk of NSAID-associated gastric ulcers, eradicate H. pylori, and treat conditions causing gastric acid hypersecretion and Donystatin (Nystatin) is a polyene ionophore antifungal used to treat cutaneous, mucocutaneous, and gastrointestinal mycotic infections, particularly those caused by Candida species.

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 and S-Prazo Feedback Form