Medicine Quality Alert: Class II Medicine Recall of Medzol (Metronidazole 400mg) Tablets, Batch Number 230940

The Pharmacy and Poisons Board has mandated Topstone Pharma Limited, to conduct an urgent recall of Medzol (Metronidazole 400mg) Tablets Batch No. 230940

From: Pharmacy and Poisons Board

Date of Recall Initiation: 11th March 2025

Recall Reference Number: REC/2025/007

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

Local Technical Representative: Topstone Pharma Limited.

Manufacturer: Shanxi Xinyitong Pharmaceutical Co., Ltd, China

Product name: Medzol

Active Pharmaceutical Ingredient: Metronidazole 400mg

Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
230940	09/2023	09/2026	100's

Brief description of the problem

The Pharmacy and Poisons Board has mandated Topstone Pharma Limited, to conduct an urgent recall of Medzol (Metronidazole 400mg) Tablets Batch No. 230940, due to out-of-specification results on the test for Uniformity of weight.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Topstone Pharma Limited to arrange the return.

Action for patients and caregivers

No further action is required by patients as this is a Retail/hospital Pharmacy and Wholesaler/Distributor level recall

Further Information

For inquiries about consignments of the impacted batch, please contact Topstone Pharma Limited at <u>topstonepharma2022@gmail.com</u> or <u>mhtemypaul@gmail.com</u> or via telephone: <u>+254 768 217670</u> and <u>+254 716</u> 338 642

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 <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 information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email: pms@ppb.go.ke