

Medicine Quality Alert: Class II Medicine Recall of Topfoliferum (Ferrous Sulphate+Folic Acid) Tablets Batch Number 240726

Topstone Pharma Ltd has initiated a voluntary recall of Topfoliferum Tablets (Ferrous sulphate+Folic acid) BN 240726

From: Pharmacy and Poisons Board
Date of Recall Initiation: 19th March 2025

Recall Reference Number: REC/2025/009

Recall Classification: Class II

Recall Level: Retail/Facility level

Manufacturer: Liaoning Huarui Union Pharmaceutical Co., Ltd, China

Local Technical Representative: Topstone Pharma Ltd

Product name: Topfoliferum

Active Pharmaceutical Ingredient: Ferrous Sulphate 200mg+Folic Acid 0.4mg

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
240726	07/2024	07/2027	100's

Brief description of the problem

Topstone Pharma Ltd has initiated a voluntary recall of Topfoliferum Tablets (Ferrous sulphate+Folic acid) BN 240726 due to market complaints of color change with some tablets becoming darker with black particles.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batch immediately. Await contact from Topstone Pharma Ltd 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. You are advised to talk to your healthcare professional if you have the above batch of Topfoliferum Tablets. The patients should continue taking other batches of the product other than the impacted batch and as prescribed by the healthcare professional.

Further Information

For inquiries about consignments of the impacted batch, please contact Sphinx Pharmaceuticals Ltd at: regulatory@topstonepharma.co.ke or by Telephone at: [+254 768 217 670](tel:+254768217670)

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 pv@ppb.go.ke or pms@ppb.go.ke
- 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