

Medicine Quality Alert: Class III Recall of Cosatrim DS (Sulfamethoxazole 800mg/Trimethoprim 160mg) Batch Number 210825 and 210828

The Pharmacy and Poisons Board has issued a mandatory recall of Cosatrim DS (Sulfamethoxazole 800mg/Trimethoprim 160mg) batches; **210825 & 210828** by Cosmos Limited.

From: Pharmacy and Poisons Board
Published: 3rd April 2023

Recall Reference Number: REC/2023/003

Recall Classification: Class III

Recall Level: Wholesaler/Distributor level

Manufacturer: Cosmos Limited

Product name: Cosatrim DS

Active Pharmaceutical Ingredient: Sulfamethoxazole 800mg/Trimethoprim 160mg

Affected Counties: All

Affected Batches

Batch Number	Date of Manufacture	Date of expiry	Pack Size
210825	11/2021	10/2024	100's
210828	11/2021	102024	100's

Brief description of the problem

The product is being recalled due to several market complaints about a quality defect involving cracking along the tablet score line. Additionally, the Board implemented post-marketing quality surveillance of medical products circulating in the Kenyan market. One of the products sampled and analyzed was Cosatrim® DS tablets (sulfamethoxazole 800 mg/trimethoprim 160 mg), from batches 210825 and 210828. The product failed to meet the specifications, as the tablets were found to be broken along the score lines and into two or more pieces.

Action for healthcare professionals

You are advised to immediately quarantine and stop supplying batches **210825** and **210828** of Cosatrim DS 960 from Cosmos Limited, Kenya, and contact Cosmos Ltd to arrange for the return of the products.

Action for patients and carers

No action is required for patients as this is a Wholesaler/Distributor level of recall. Patients currently prescribed Cosatrim DS (Sulfamethoxazole 800mg/Trimethoprim 160mg) batches; **210825** and **210828** should contact their healthcare professional. The patients should continue taking other

batches of the product other than the impacted batches and as prescribed by the healthcare professional.

Further Information

For any stock enquiries please contact Cosmos Limited, Kenya at: info@cosmos-pharm.com or via telephone: + 254 (0) 709 864 000,+ 254 (0) 722 333 834,+ 254 (0) 733 666 834

You are advised to 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 pv@ppb.go.ke or pms@ppb.go.ke
- 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