Medicine Quality Alert: Class II Recall of Oralex C Mouthwash Batch No. L220077

The Pharmacy and Poisons Board has mandated Krishna Chemist Limited to initiate the urgent recall of Oralex C Mouthwash Batch No.L220077

From: Pharmacy and Poisons Board

Published: 18/09/2023

Recall Reference Number: REC/2023/013

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

Local Technical Representative: Krishna Chemist Limited

Manufacturer: Curis Lifesciences PVT. Ltd

Product name: Oralex C Mouthwash

Active Pharmaceutical Ingredient: Chlorhexidine Gluconate &

Benzydamine Hydrochloride mouthwash

Affected Counties: All

Affected batch

Batch	Date of	Date of	Pack Size
Number	Manufacture	Expiry	
L220077	06/2022	05/2025	200 ml

Brief description of the problem

The product is being recalled following out-of-specification results. The product failed to comply with the specifications on the description as per market authorization requirements.

Action for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining stock and await contact from Krishna Chemist Limited, Kenya, who will arrange for the collection of the product.

Action for patients and carers

Patients currently prescribed Oralex C Mouthwash Batch No.L220077 should be contacted by their prescribing 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 inquiries about consignments of the impacted batches, please contact Krishna Chemist Limited at: regulatory@krishnachemists.com or Tel: +254 722 366 988, +254 714 714 178, +254 715 946 380

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 Pharmacy and Poisons Board by email: pms@ppb.go.ke