Medicine Quality Alert: Class II Recall of Efinox 1% (Ephedrine Hydrochloride Nasal Drops) Batch Number 82979 and 82978

The Pharmacy and Poisons Board and Laboratory and Allied Limited have initiated the urgent recall of Efinox 1%, Batch No. 82979 and 82978 due to out-of-specification results on assay.

From: Pharmacy and Poisons Board

Published: 01/08/2024

Recall Reference Number: REC/2024/019

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

Manufacturer: Laboratory and Allied Limited

Product name: Efinox 1%

Active Pharmaceutical Ingredient: Ephedrine Hydrochloride Nasal Drops

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
82979	02/2023	01/2025	5ml bottle
82978	02/2023	01/2025	5ml bottle

Brief description of the problem

The product is being recalled following out-of-specification results (OOS) on assay.

Action for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and await contact from Laboratory and Allied Limited, Kenya, who will contact healthcare professionals directly to arrange the return.

Action for patients and caregivers

Patients currently prescribed Efinox 1% (Ephedrine Hydrochloride Nasal Drops) Batch No. 82979 and 82978, should be contacted by their prescribing healthcare professional. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options.

Further Information

For enquiries about consignments of the impacted batch, please contact Laboratory and Allied Ltd, at: pv@laballied.com, or via telephone: 0722877676, 0722406189

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

For any further enquiries 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