Medicine Quality Alert: Class II Medicine Recall of Steramine (Betamethasone and Dexchlorpheniramine) Tablets Batch No. BPL783A and BPL409A

The Pharmacy and Poisons Board has mandated Biopharma Ltd to initiate an urgent recall of Steramine (betamethasone and dexchlorpheniramine) tablets batch no. BPL783A and BPL409A

From: Pharmacy and Poisons Board Date of Recall Initiation: 20/08/2025

Recall Reference Number: REC/2025/029

Recall Classification: Class II Recall Level: Retail/Facility level Manufacturer: Biopharma Ltd Product name: Steramine Tablets

Active Pharmaceutical Ingredient: betamethasone USP 0.25 mg and

dexchlorpheniramine USP 2 mg

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
BPL783A	04/2024	03/2027	30s
BPL409A	10/2023	09/2026	30s

Brief description of the problem

The product batches are being recalled due to failure to comply with identification by HPLC test for betamethasone and assay for both betamethasone and dexchlorpheniramine Maleate. The product batches were sampled during risk-based post-marketing surveillance activities.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Biopharma 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 batches of Steramine tablets.

Further Information

For inquiries about consignments of the impacted batches, please contact Biopharma Ltd at: info@biopharmaltd.com or by Telephone at: +254 726 999 888

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 <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 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