

Medicine Quality Alert: Class III Medicine Recall of Bisotrol (Bisoprolol 5mg) Tablets, Batch Number JJI023002

Sai Pharmaceuticals Limited, Kenya, has initiated an urgent voluntary recall of Bisotrol (Bisoprolol 5mg) Tablets BN JJI023002

From: Pharmacy and Poisons Board

Date of Recall Initiation: 3rd January 2025

Recall Reference Number: REC/2025/001

Recall Classification: Class III

Recall Level: Wholesale Level

Local Technical Representative: Sai Pharmaceuticals Limited, Kenya.

Manufacturer: Ipca Laboratories Ltd, India

Product name: Bisotrol

Active Pharmaceutical Ingredient: Bisoprolol 5mg

Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
JJI023002	02/2023	01/2026	100's

Brief description of the problem

The product is being recalled following out-of-specification (OOS) results observed in the Related Substances test of Bisotrol - 5 Tablet at 12M on 30C/75% stability conditions.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Sai Pharmaceuticals Limited to arrange the return.

Action for patients and caregivers

No further action is required by patients as this is a Wholesaler/Distributor level recall

Further Information

For inquiries about consignments of the impacted batches, please contact Sai Pharmaceuticals Limited at info@saipharm.com or sales@saipharm.com. or via telephone: <tel:+254-20-4454301/2/3>, <tel:+254-733-741-911>, <tel:+254-721-243-322>

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