

Medicine Quality Alert: Class II Medicine Recall of Betamol (Paracetamol 500mg) Tablets Batch No. 01215PT

The Pharmacy and Poisons Board has mandated Sphinx Pharmaceuticals Ltd, Kenya to conduct an urgent recall of Betamol (Paracetamol 500mg) Tablets Batch No. 01215PT

From: Pharmacy and Poisons Board
Date of Recall Initiation: 11th March 2025

Recall Reference Number: REC/2025/008
Recall Classification: Class II
Recall Level: Retail/Facility level
Manufacturer: Sphinx Pharmaceuticals Ltd, Kenya
Product name: Betamol
Active Pharmaceutical Ingredient: Paracetamol 500mg
Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
01215PT	09/2023	08/2026	1000 Tablets in a container

Brief description of the problem

The Pharmacy and Poisons Board has mandated Sphinx Pharmaceuticals Ltd, Kenya to conduct an urgent recall of Betamol (Paracetamol 500mg) Tablets Batch No. 01215PT due to non-compliance with the specifications on the test for Uniformity of weight.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batch immediately. Await contact from Sphinx Pharmaceuticals 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 batch of Betamol (Paracetamol 500mg) Tablets. The patients should continue taking other batches of the product other than the impacted batch and as prescribed by the healthcare professional.

Further Information

For inquiries about consignments of the impacted batch, please contact Sphinx Pharmaceuticals Ltd at: sphinx@sphinx.co.ke or by Telephone at: [+254 722 565 305](tel:+254722565305)

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 pv@ppb.go.ke or pms@ppb.go.ke
- 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