Medicine Quality Alert: Class II Medicine Recall of Ibuflam plus Suspension 60ml (Paracetamol 125mg, Ibuprofen 100mg per 5ml) Batch No. 0424097 and 0824011

Biodeal Laboratories Limited has initiated an urgent voluntary recall of Ibuflam plus Suspension 60ml (Paracetamol 125mg, Ibuprofen 100mg per 5ml), Batch No. 0424097 and 0824011

From: Pharmacy and Poisons Board

Date of Recall Initiation: 7th November 2025

Recall Reference Number: REC/2025/034

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

Manufacturer: Biodeal Laboratories Limited, Kenya **Product name:** Ibuflam Plus Suspension 60ml

Active Pharmaceutical Ingredient: Paracetamol 125mg, Ibuprofen 100mg

per 5ml

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
0424097	04/2024	03/2027	60ml
0824011	08/2024	07/2027	60ml

Brief description of the problem

Biodeal Laboratories Limited, Kenya, initiated a voluntary recall due to the product's failure to meet the specification for PH and the low contents of paracetamol.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing, or use of the above batch immediately. Await contact from Biodeal Laboratories Limited, Kenya, 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 Ibuflam Plus Suspension 60ml. The patients should continue taking other batches of the product, other than the impacted batch, and as prescribed by the healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions

should also be reported via <u>pv@pharmacyboardkenya.org</u>; regulatory@pharmacyboardkenya.org

Further Information

For medical information inquiries, please contact Biodeal Laboratories Ltd, Kenya,at:<u>regulatoryaffairs@biodealkenya.com</u>, , , , , <u>chriskibathi@biodealkenya.com</u>, <u>freshia@biodealkenya.com</u> or via telephone: +254 722 214178

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 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