# Medicine Quality Alert: Class I Medicine Recall Lumidol Injection (Paracetamol 1% W/V injection) Batch Numbers CM4594007, CM4594008, and CM4594009

The Pharmacy and Poisons Board has mandated Zawadi Healthcare Ltd to recall Lumidol Injection (Paracetamol 1% W/V injection) Batch Numbers CM4594007, CM4594008, and CM4594009

From: Pharmacy and Poisons Board Date of Recall Initiation: 24th April 2025

Recall Reference Number: REC/2025/016 Recall Classification: Class I Recall Level: Retail/Facility level Manufacturer: KamlaAmrut Pharmaceutical LLP, India. Local Technical Representative (LTR): Zawadi Healthcare Ltd Product name: Lumidol Active Pharmaceutical Ingredient: Paracetamol 1% W/V injection Affected counties: All

## Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
CM4594007	11/2024	10/2026	100ml
CM4594008	11/2024	10/2026	100ml
CM4594009	11/2024	10/2026	100ml

### Brief description of the problem

The product is being recalled due to market complaints about the color change of the product to black.

### Action for healthcare professionals

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

### **Further Information**

For inquiries about consignments of the impacted batch, please contact Zawadi Healthcare Ltd at: <u>regulatory@zawadihealthcare.com</u> or

 $\underline{bhatt@zawadihealthcare.com},$  or by Telephone at: +254 784 882 278 / +254 784 882 279

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:

- <u>https://pv.pharmacyboardkenya.org/users/mpublic</u>
- 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 on 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 <u>pms@ppb.go.ke</u>