

Medicine Quality Alert: Class II Medicine Recall of Haemacel (Polygeline) Injection, Batch Number HA3004

Piramal Pharma Limited has initiated an urgent voluntary recall of Hemacel (Polygeline) Injection Batch Number HA3004

From: Pharmacy and Poisons Board
Published: 22nd March 2024

Recall Reference Number: REC/2024/006

Recall Classification: Class II

Recall Level: Retail/Facility Level

Local Technical Representative (LTR): Galaxy Pharmaceutical Ltd

Manufacturer: Piramal Pharma Limited

Product name: Haemacel 500ml Injection

Active Pharmaceutical Ingredient: Polygeline (3.5% Colloidal infusion solution of Polygeline with electrolytes for intravenous administration)

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
HA3004	11/2023	10/2026	500 ml

Brief description of the problem

The product is being recalled, following a complaint concerning bottle leakages and damage to mono cartons of Haemacel 500mg Injection from hospitals, which was indicative of a potential breach of integrity.

Action for healthcare professionals

You are advised to immediately quarantine and stop supplying the remaining stocks of the impacted batches of the product. Galaxy Pharmaceutical Ltd will contact you to arrange for the return of the product.

Action for patients and caregivers

No further action is required by patients as this product is usually administered by healthcare professionals in a hospital setting, and the recall is a Retail/Hospital Pharmacy and Wholesaler/Distributor level recall.

Further Information

For inquiries about consignments of the impacted batches, please contact Galaxy Pharmaceutical Ltd at: info@galaxypharma.co.ke or pvigilance@galaxypharma.co.ke or by Telephone at +254 3748551/2/3/4

You are advised to 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 inquiries 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