Medicine Quality Alert: Class II Recall of Lasideal tablets (Furosemide 40mg) Batch Number 0621116

Biodeal Laboratories Limited is recalling batch 0621126 of Lasideal tablets, due to noted black spots on the tablets.

From: Pharmacy and Poisons Board Published: 15/11/2023

Recall Reference Number: REC/2023/017 Recall Classification: Class II Recall Level: Retail/Facility level Manufacturer: Biodeal Laboratories Limited, Kenya Product name: Lasideal Active Pharmaceutical Ingredient:Furosemide 40mg Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
0621116	06/2021	05/2024	100's

Brief description of the problem

Biodeal Laboratories Limited is recalling batch 0621116 of Lasideal tablets due to noted black spots on the tablets. Further review of retained samples of this batch revealed the presence of brown spots as well.

The manufacturer conducted further examinations, such as chemical analysis of this particular batch and others available in the market, along with induced degradation through oxidation and alkali treatment, which revealed that this batch contained a reduced amount of active pharmaceutical ingredient (API) compared to all other batches, despite it falling within the prescribed limits.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing, or use of batch 0621126 immediately and contact Biodeal Laboratories Limited team to arrange the return of the product.

Action for patients and caregivers

Patients should continue to take medicines from other batches of this product other than the impacted batch and as prescribed by their healthcare professional.

Further Information

For any lasideal stock enquiries please contact the Biodeal Laboratories Limited P.O. Box 32040 – 00600 Nairobi, by email at <u>qa@biodealkenya.com</u>, <u>chriskibathi@biodealkenya.com</u> or via telephone at 0720333829 / 0734333829.

Promptly report any case/s of suspected substandard and falsified product or adverse reactions or insufficient control of symptoms to the nearest healthcare facility or the Pharmacy and Poisons Board through the following channels:

- <u>https://pv.pharmacyboardkenya.org/users/mpublic</u>
- USSD code at *271#
- Email: <u>pv@ppb.go.ke</u> and <u>pms@ppb.go.ke</u>
- Telephone number. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further enquiries contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at <u>pms@pppb.go.ke</u>