Medicines Quality alert: Class II Recall of Biodopa 250mg tablets Batch Number 0321077, 0421142 and 0421112

Biodeal Laboratories Limited is recalling batches *0321077*, *0421142*, and *0421112* of Biodopa 250mg Tablets due to color change and inconsistent color of the tablets.

From: Pharmacy and Poisons Board

Published: 06/04/2022

Recall Reference Number: REC/2022/04

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

Company name: Biodeal Laboratories Limited, Kenya

Product name: Biodopa 250mg Tablets

Active Pharmaceutical Ingredient: Methyldopa

Affected batches:

Batch number	Expiry date	Pack Size
0321077	02/2024	100's
0421142	03/2024	100's
0421112	03/2024	100's

Brief description of the problem

The Pharmacy and Poisons Board has received market complaints of color change/molding of Biodopa tablets, Batch No *0321077* and *0421112*. Biodeal Laboratories Ltd initiated a voluntary recall of the above batches, plus *0421142* as a precautionary measure.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for patients and caregivers

Biodopa 250mg tablets are used in the management of high blood pressure. You are advised to talk to your healthcare professional if you have the above batches of Biodopa 250mg Tablets. The patients should continue taking other batches of the product other than the impacted batches and as prescribed by the healthcare professional.

Further Information

For all inquiries on consignments of the impacted batches, please contact Biodeal Laboratories Limited by email at regulatoryaffairs@biodealkenya.com or by phone +254 720 333 829

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:

- https://pv.pharmacyboardkenya.org/users/mpublic
- USSD code at *271#
- Email: pv@ppb.go.ke and pms@ppb.go.ke
- 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 pms@ppb.go.ke