

Medicine Quality Alert: Class II Medicines Recall Notification: Recall of Nycodeal Oral suspension batch 0523083 and 0523084

Biodeal Laboratories Limited has initiated an urgent recall of batch 0523083 and 0523084 of Nycodeal Oral suspension 30ml (Nystatin 100000 I.U /ml, 30ml)

From: Pharmacy and Poisons Board
Published: 7th December 2023

Recall Reference Number: REC/2023/018

Recall Classification: Class II

Recall Level: Retail/Facility level

Manufacturer: Biodeal Laboratories Limited, Kenya

Product name: Nycodeal Oral Suspension

Active Pharmaceutical Ingredient: Nystatin 100000 I.U /ml

Affected Counties: All

Affected batches

Batch Number	Date of Manufacture	Date of expiry	Pack Size
0523083	05.2023	04.2025	30ml
0523084	05.2023	04.2025	30ml

Brief description of the problem

Following routine market surveillance activities, the Pharmacy and Poisons Board (PPB) detected out-of-specification (OOS) results for Nycodeal Batch No 0523083 and 0523084.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from the Biodeal Laboratories Limited team to arrange for the return.

Action for patients and caregivers

Patients should not continue to take medicines from this batch and should return the medication to the prescriber.

Further Information

For any Nycodeal stock enquiries please contact the Biodeal Laboratories Limited P.O. Box 32040 – 00600 Nairobi, by email at qa@biodealkenya.com, chriskibathi@biodealkenya.com or via telephone at 0720333829 or 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:

- <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 information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email at pms@ppb.go.ke