Medicine Quality Alert: Class II Medicine Recall of AmoxiClav Denk 1000/125mg powder for oral suspension

Denk Pharma GmbH & Co KG is recalling Amoxiclav Denk (Amoxicillin+Clavulanic Acid) 1000/125mg powder for oral suspension, Batch Number 27608

From: Pharmacy and Poisons Board
Published: 15th May 2024

Recall Reference Number: REC/2024/012
Recall Classification: Class II
Recall Level: Retail/Facility Level
Local Technical Representative (LTR): Laborex Ltd
Manufacturer: Denk Pharma GmbH & Co KG, Germany
Product name: AmoxiClav-Denk
Active Pharmaceutical Ingredient: Amoxicillin & Clavulanic Acid 1000/125mg
Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
27608	05/2023	05/2026	12's

Brief description of the problem
Denk Pharma detected an out-of-specification result regarding AmoxiClav-Denk 1000/125, powder for oral suspension, Batch Number 27608. In an ongoing stability study, visual changes in the appearance of a small number of individual sachets were detected.

Action for healthcare professionals
Quarantine all remaining stock and stop further distribution, sale, issuing, or use of the above batches immediately. Await contact from Laborex 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-level recall.

Further Information
For inquiries about consignments of the impacted batch, please contact Surgipharm Limited at: pv.ke@laborex-healthcare.com or sagak@laborex-healthcare.com or Tel: +254 722 33 58 58, +254 20 69 39 00/137/162

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:

- https://pv.pharmacyboardkenya.org/users/mpublic
- Mobile application: mPvERS both Android and iOS
- USSD code at *271#
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049

For any further enquiries and feedback on the product recall, kindly contact the post-marketing surveillance unit of The Pharmacy and Poisons Board Kenya “the Board” via email at pms@ppb.go.ke