Medicine Quality Alert: Class II Medicine Recall of Denk-Air Junior (Montelukast 4mg) Batch number 27084

The Denk Pharma GmbH & Co. KG has initiated an urgent voluntary recall of Denk-Air Junior 4 mg (Montelukast 4mg) Batch number **27084**

From: Pharmacy and Poisons Board
Published: 1st June 2023

Recall Reference Number: REC/2023/007
Recall Classification: Class II
Recall Level: Retail/Facility level
Local Technical Representative: Laborex Kenya Limited
Manufacturer: Denk Pharma GmbH & Co. KG, Germany
Product name: Denk-Air Junior 4 mg
Active Pharmaceutical Ingredient: Montelukast 4mg
Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
27084	03/2022	03/2025	28's

Brief description of the problem
The product is being recalled, following an out-of-specification (OOS) result during an ongoing stability study. Quality control analysis confirmed that the product did not meet the necessary standards outlined in its market authorization. Specifically, the batch contained up to 0.73% of two initially unknown impurities, whereas the valid shelf-life limit at that time was 0.5 %.

Action for healthcare professionals
Stop supplying the above batches immediately. Quarantine all remaining stock and Health Classique Limited will contact healthcare professionals directly to arrange the return..

Action for patients and carers
Patients currently prescribed Denk-Air Junior (Montelukast 4mg) batch number 27084 should contact their healthcare professional. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options.

Further Information
For stock inquiries please contact Laborex Kenya Ltd by email at pv.ke@laborex-healthcare.com and Health Classique Limited at: logistics@healthclassique.com and by Telephone at: +254 722 33 58 58 and 0207866067 respectively.

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