

Medicine Quality Alert: Class II Recall of Mespurin 1000mg IM, 2000mg IV, and 500mg IV Injection

Acino AG Munich is initiating a voluntary recall of Mespurin 500mg IV, 1000mg IM, and 2000mg IV, Batch number Z0142Z0153, Z0149, Z0057, Z0107, and Z0086Z0115.

From: Pharmacy and Poisons Board
Published: 15th June 2023

Recall Reference Number: REC/2023/008

Recall Classification: Class II

Recall Level: Retail/Facility level

Marketing Authorization Holder: Acino AG Munich

Local Technical Representative: Laborex Kenya Ltd

Product name: Mespurin 500mg IV, 1000mg IM and 2000mg IV

Active Pharmaceutical Ingredient: Ceftriaxone 1000mg IM, Ceftriaxone 2000mg IV, Ceftriaxone 500 mg IV

Affected Counties: All

Affected batches

Batch Number	Date of Manufacture	Date of expiry
Z0030Z0129	01/02/2022	01/02/2025
Z0149	01/09/2022	01/09/2025
Z0057	01/04/2022	01/04/2025
Z0107	01/06/2022	01/06/2025
Z0086Z0115	01/05/2022	01/05/2025

Brief description of the problem

This recall is initiated as a precautionary measure following the sporadic discovery of visible particles in the reconstituted powder of the product, in the course of an ongoing investigation by Acino and the related Contract Manufacturing Organisation. According to the investigation's preliminary outcome, the particles consist of polystyrene.

Action for healthcare professionals

You are advised to immediately stop supplying and quarantine the impacted batches of the product. Goodman Agencies and Laborex Kenya will contact healthcare professionals directly to arrange the return of the products.

Action for patients and carers

No further action is required by patients as this product is usually administered by healthcare professionals in a hospital setting, and the recall is a Retail/Facility level recall.

Further Information

For stock and other enquiries please contact Acino AG Munich. at: qa.germany@acino.swiss. Tel: +49 893221280-10; **OR** GoodMan Agencies jmunqa@goodman.co.ke Tel: +254 20 4446664/5/6 **OR** Laborex Kenya Ltd at: pv.ke@laborex-healthcare.com or saga@laborex-healthcare.com Tel: +254 722335858/+25420693900/137/162

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 at pms@ppb.go.ke