

Medicine Quality Alert: Class I Medicine Recall of ALL batches of Tamedol Suspension (Paracetamol 120mg/5ml)

The Pharmacy and Poisons Board has mandated Biopharma Limited, Kenya, to initiate an urgent recall of Tamedol Suspension (Paracetamol 120mg/5ml, 60mls), of **ALL** batches in the Market.

From: Pharmacy and Poisons Board

Published: 18/09/2023

Recall Reference Number: REC/2023/011

Recall Classification: Class I

Recall Level: Consumer level

Manufacturer: Biopharma Limited, Kenya.

Product name: Tamedol Suspension

Active Pharmaceutical Ingredient: Paracetamol 120mg/5ml

Affected Batches: All Batches in the Market

Affected counties: All

Brief description of the problem

The Pharmacy and Poisons Board (PPB) received multiple market complaints on quality defects of several batches of Tamedol oral suspension (Paracetamol suspension, 120mg/5ml, 60 ml) manufactured by Biopharma LTD, Kenya. In response to these concerns, the PPB upon investigation, indeed confirmed that the product failed to meet the prescribed market authorization requirements and initiated mandatory recall of the product by the manufacturer.

Action for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and await contact from Biopharma Limited, Kenya, who will arrange the return.

In light of the above findings, the PPB advised all pharmaceutical outlets, healthcare facilities, healthcare professionals, and members of the public to quarantine the product and stop all further distribution, sale, issuing, or use of the product.

Action for patients and carers

Patients currently prescribed Tamedol Suspension (Paracetamol 120mg/5ml) should be contacted by their prescribing healthcare professional. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options.

Members of the public are urged to return the product to their nearest healthcare facility, while healthcare facilities are instructed to return the products to their respective suppliers.

Further Information

For inquiries about consignments of the impacted batches please contact Biopharma Ltd at: info@biopharmaltd.com, enderebakabera@gmail.com or Tel: +254 717 768 794

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