

# Medicine Quality Alert: Class I Medicine Recall of Benylin Paediatric Syrup Batch No 329304

The Pharmacy and Poisons Board has mandated Surgipharm Ltd, Kenya, to initiate an urgent recall of Benylin Paediatric Syrup Batch No 329304.

From: Pharmacy and Poisons Board

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**Recall Reference Number:** REC/2024/010

**Recall Classification:** Class I

**Recall Level:** Consumer-level

**Local Technical Representative:** Surgipharm Ltd

**Manufacturer:** Johnson & Johnson (Pty), South Africa

**Product name:** Benylin Paediatric Syrup

**Active Pharmaceutical Ingredient:** Diphenhydramine HCL 7mg/5ml

**Affected counties:** All

## Affected Batches

Batch Number	Date of Manufacture	Date of expiry	Pack Size
329304	05/2021	04/2024	100 ml

## Brief description of the problem

The Pharmacy and Poisons Board (PPB) is in receipt of information on the medical product alert and recall of Benylin pediatric 100mls cough syrup Batch No **329304** by the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria; due to quality concerns. The quality concerns are unacceptable high level of diethylene glycol that was detected following laboratory analysis by NAFDAC. Diethylene glycol is a contaminant which is toxic to humans when consumed and can prove fatal. Toxic effects can include abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.



### **Action for healthcare professionals**

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Surgipharm Ltd to arrange the return.

### **Action for patients and caregivers**

Patients and members of the public are advised to return the product to the nearest healthcare facility.

### **Further Information**

For inquiries about consignments of the impacted batch, please contact Surgipharm Limited at: [info@surgipharm.com](mailto:info@surgipharm.com), [sales@surgipharm.com](mailto:sales@surgipharm.com) or [marketing@surgipharm.com](mailto:marketing@surgipharm.com) or Tel: +254 722 204 707, +254 734 224 228

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>
- USSD code at \*271#
- Email [pv@ppb.go.ke](mailto:pv@ppb.go.ke) or [pms@ppb.go.ke](mailto:pms@ppb.go.ke)
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further enquiries contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at [pms@ppb.go.ke](mailto:pms@ppb.go.ke)