

PHARMACY AND POISONS BOARD

PUBLIC ALERT ON BENYLIN PAEDIATRIC 100MLs COUGH SYRUP, **BATCH NO. 329304 MANUFACTURED BY JOHNSON & JOHNSON (Pty), SOUTH AFRICA**

The Pharmacy and Poisons Board (PPB) wishes to inform the public that it has received information regarding a medical product alert and recall of Benylin paediatric 100mls cough syrup **Batch No 329304**, by the National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria. This cough syrup manufactured by Johnson & Johnson (Pty), South Africa, is being recalled due to quality concerns arising from an unacceptable high level of diethylene glycol detected through laboratory analysis conducted 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, diarrhoea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death.

The product details is as follows;

S/N	Name of the product	Batch Number	Date of manufacture	Date of expiry
	Benylin Paediatric 100mls syrup	329304	May 2021	April 2024

Photos of the product



Following receipt of this information the PPB has immediately commenced investigations. The PPB also initiated rapid response, which includes sampling of batches of Benylin paediatric 100mls syrup that are within shelf life for the purpose of screening of the levels of Ethylene glycol and diethylene glycol.

Subsequent implementation of regulatory actions will be based on the laboratory findings.

In view of the above, the PPB advises all pharmaceutical outlets, healthcare facilities, healthcare workers and members of the public to immediately quarantine the product and STOP distribution, sale, issuing or use of the product. Furthermore, members of public are advised to return the product to the nearest healthcare facility, while healthcare facilities are advised to return the products to the respective suppliers. It is IMPORTANT TO NOTE that this alert affects ONLY the impacted **BATCH NO 329304** of Benylin pediatric 100mls syrup.

The public or patients who experience adverse reaction/events following the use of this product in children, are advised to direct such patients for immediate medical attention from a qualified healthcare professional.

The PPB would like to assure the public that we have established mechanisms to ensure that medicines supplied to Kenyan market meet the required Quality, Safety and Efficacy standards.

We encourage the public to be vigilant at all times and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and the Pharmacy and Poisons Board via the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>,
- Mobile application: mPvERS both android & iOS and
- USSD code: at *271# or
- Email; pms@ppb.go.ke Tel No. 0795743049.



Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER

11th April 2024