



LET_LSE/PMS/0004/12/23

All correspondence should be addressed to the Director General

In reply, please quote

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 14th December 2023

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, Patients, General Public

**URGENT PRODUCT RECALL:
BGMET (METFORMIN) TABLETS BP 500MG BATCH NO. KBT018 MANUFACTURED
BY BLISS GVS PHARMA PVT. LTD., INDIA**

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal health protection.

ZAMRA wishes to alert patients, healthcare professionals, the pharmaceutical industry and the general public that it has initiated a **STATUTORY RECALL** of one batch of **BGMET (Metformin) Tablets BP 500mg** (see product details below), due to non-compliance with respect to Assay Test.

This implies that the product has a lower active pharmaceutical ingredient than the stated amount per tablet. As a consequence, using the product may lead to under-dosing and may affect the desired treatment outcome.

Product details:

S/N	Name of Product	Manufacturer	Batch Number	Mfg. Date	Expiry Date
1.	BGMET Metformin Tablets BP 500mg	Bliss GVS Pharma. Ltd., India	KBT018	08/2022	07/2025

Therefore, ZAMRA has instructed Yash Pharmaceuticals Limited, the importer of the product, to immediately recall the product from circulation. In the event that you are in possession of the above-mentioned product, please return it to your healthcare provider or supplier who should in turn quarantine the product pending collection by the importer for disposal.

If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by: phone number +260 211 432 356; WhatsApp line +260 956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL

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Report Adverse Reactions to:
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Website: www.zamra.co.zm