

B/279/35/05/2026

CIRCULAR No. 05 of 2026

Date: 19th March 2026

TO: ALL LICENSED PHARMACIES, WHOLESALERS, PUBLIC AND PRIVATE CLINICS AND HOSPITALS, AND CONSUMERS

RE: PUBLIC ALERT ON THE RECALL OF MEGLUMINE AMIDOTRIZOATE/ SODIUM AMIDOTRIZOATE 0.3 / 0.6 / 0.76 G/ML (UROGRAFIN 60%) SOLUTION FOR INJECTION

The Medicines Control Authority of Zimbabwe (MCAZ) would like to inform all stakeholders of a critical communication received from Bayer Pty Ltd, South Africa, regarding a voluntary recall of specific batches of **MEGLUMINE AMIDOTRIZOATE/ SODIUM AMIDOTRIZOATE 0.3 / 0.6 / 0.76 G/ML (UROGRAFIN 60%) SOLUTION FOR INJECTION**, a contrast agent used for X-ray and diagnostic imaging. The recall applies to **ALL batches** of Urografin 60%, which were manufactured from **October 2020 to March 2025**.

This recall follows confirmatory testing which revealed the presence of an impurity known as **N-Nitroso-Meglumine (NO-Meglumine)** in the product at levels exceeding the newly established safety limits. Recent in-vivo (animal) studies have confirmed that the impurity **N-Nitroso-Meglumine** is genotoxic and potentially carcinogenic. Based on this new scientific evidence, the acceptable daily intake limit for this impurity has been significantly reduced to ensure patient safety.

While the Authority confirms that this product was registered in Zimbabwe in 2018, our importation records show no evidence of its entry into the country between 2020 and 2026. Nevertheless, there remains a concern that the affected batches of Urografin 60% could have been introduced into the local market through unauthorized or illegal channels. As a precautionary measure, the Authority is therefore issuing a formal alert for this product.

In the unlikely event that members of the public encounter Urografin 60%, they are urged to immediately notify the Authority or a healthcare provider and refrain from administering it to patients. Stakeholder cooperation is vital to safeguard public access to safe and quality medicines. The Authority will intensify market surveillance through enhanced premises inspections and public awareness to prevent the circulation of this product.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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R.T. RUKWATA (MR)

DIRECTOR GENERAL

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