

All correspondence should be addressed to the Director General



In reply, please quote

# ZAMBIA MEDICINES REGULATORY AUTHORITY

LET\_LSE\_PMS\_0015/03/26

## PUBLIC NOTICE

Date: 26<sup>th</sup> March 2026

To: Pharmaceutical wholesalers, Retailers, Health facilities, Radiologists, Urologists and other healthcare professionals

### URGENT PUBLIC ALERT:

#### RECALL OF UROGRAFIN SOLUTION FOR PARENTERAL USE BY BAYER (PVT) LIMITED, SOUTH AFRICA

FOR IMMEDIATE RELEASE – 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 ensure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

The Authority would like to inform pharmaceutical outlets, health facilities and healthcare professionals such as radiologists, urologists and others that Bayer (Pty) Limited, South Africa is conducting **RECALL** of **ALL** batches of UROGRAFIN (Meglumine amidotriazoate and Sodium amidotriazoate, 30%, 60%, 76%) solution for injection due to formation of a nitrosamine impurity (**NO-Meglumine**) in the products.

#### Registered Products:

S/N	Name of Product	Registration No.
1	UROGRAFIN 30%	140/081L
2	UROGRAFIN 60%	140/019L
3	UROGRAFIN 76%	140/020L
4	GASTROGRAFIN	-

#### WHAT IS UROGRAFIN/GASTROGRAFIN

UROGRAFIN (Active Pharmaceutical Ingredient: Amidotriazoate) is an iodinated, water-soluble, radiopaque contrast medium used in X-ray imaging, CT scans, and angiographic examinations. It is commonly formulated as a combination of Sodium amidotriazoate and Amidotriazoate meglumine. It acts as a diagnostic agent to enhance visualization of blood vessels and tissues. **These products are strictly for use in healthcare settings only by Radiologists, Urologists and other trained healthcare professionals.**

#### NITROSAMINE RISK

Nitrosamine impurities are chemical compounds classified as probable human carcinogens, which means long-term exposure above safe levels could increase cancer risk. They exist naturally in low levels in water and some foods. In medicines, they are unintended by-products formed during drug manufacturing or storage, particularly when amines react with nitrites.

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**Report Adverse Reactions to:**  
Pharmacovigilance Unit, Lusaka  
Tel: +260 211 432 356  
E-mail: [npvu@zamra.co.zm](mailto:npvu@zamra.co.zm)  
Website: [www.zamra.co.zm](http://www.zamra.co.zm)

An investigation by Bayer on all formulations of meglumine amidotrizoate and sodium amidotrizoate (Gastrografin, Urografin) found that NO-Meglumine exceeded the established limits for its acceptable intake. Therefore, a potential safety risk cannot be fully excluded.

## ALTERNATIVES

Bayer (Pty) Limited has proposed use of **alternative contrast agents** or use of contrast-enhanced X- ray examinations, such as ultrasound (with or without contrast media) or magnetic resonance imaging (with or without contrast media). However, Bayer (Pty) Limited is investigating the root cause and any potential measures to **ensure re-supply as soon as possible**.

## BATCHES ON THE MARKET

The table below shows batches representative for all batches on the market with a manufacturing date between 10/2020 and 03/2025, covering the whole shelf life of the product (up to 60 months).

S/N	Name of Product	Manufacturer	Batch No.	Expiry Date
1.	Gastrografin	Bayer (Pvt) Ltd, South Africa	MA04UU6	31/05/2027
			MA04VTR	31/05/2027
			MA04RN3	31/01/2027
2.	Urografin 30%	Bayer (Pvt) Ltd, South Africa	MA04VPS	30/04/2030
			MA04V7D	30/04/2030
			MA04SJ4	30/09/2029
3.	Urografin 60%	Bayer (Pvt) Ltd, South Africa	MA04R29	31/08/2029
4.	Urografin 76%	Bayer (Pvt) Ltd, South Africa	MA04SRF	30/09/2029
			MA04X07	30/09/2029

## ACTIONS REQUIRED

All pharmaceutical outlets, health facilities (private and public) in possession of any of these products should return them to their suppliers for collection by the importer(s) for disposal. Bayer is working to further investigate the source and levels of nitrosamine impurities in Gastrografin/Urografin batches, to enable implementation of corrective actions to minimize nitrosamine presence.

Should you need further clarification, please do not hesitate to contact our Secretariat.



Makomani Siyanga (Mr.)  
**DIRECTOR-GENERAL**