Dear Healthcare Professional

URGENT MEDICINE RECALL (CLASS II TYPE B)

Class II recall is intended for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers, and dispensers

Risk for the formation of nitrosamines (N-Nitroso-Meglumine)
Voluntary recall of all formulations as a precautionary measure

Product Name	Registration No.
1. GASTROGRAFIN	H/28/2842
2. UROGRAFIN 30%	F/28/606
3. UROGRAFIN 60 %	H/28/2843
4. UROGRAFIN 76 %	H/28/2844

Bayer (Pty) Ltd, in consultation with the South African Health Products Regulatory Authority (SAHPRA), is conducting a Class II Type B recall of the following batches listed in the Table below and all other non-expired older batches which are not listed in the Table below, of Gastrografin and Urografin currently in the market;

Product Name	Batch Number	Expiry Date
Gastrografin	MA04UU6	31/05/2027
	MA04VTR	31/05/2027
	MA04RN3	31/01/2027
Urografin 30 %	MA04VPS	30/04/2030
	MA04V7D	30/04/2030
	MA04SJ4	30/09/2029
Urografin 60 %	MA04R29	31/08/2029
Urografin 76 %	MA04SRF	30/09/2029
	MA04X07	30/09/2029

Reason for Recall:

- Bayer has detected a risk for the formation of nitrosamine (N-Nitroso-Meglumine) in Gastrografin/Urografin.
- The evaluation of N-Nitroso-Meglumine showed a potential of mutagenicity in a mouse study.
- All formulations of meglumine amidotrizoate and sodium amidotrizoate (Gastrografin, Urografin) are exceeding the established limits for the acceptable intake of N- Nitroso-Meglumine in most tested batches.
- A potential safety risk for the patient cannot be fully excluded, although clinical manifestations have not been detected.
- As a precautionary measure, Bayer has decided to voluntarily recall all formulations of Gastrografin/Urografin (meglumine amidotrizoate and sodium amidotrizoate).

10 March 2026

Regulatory Affairs Department

Bayer (Pty) Ltd
Reg No: 1968/011192/07

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Directors:
J LeVinson Garduño[1]
Dr S Thoenes[1]
M P Eggert[1] [non-executive]
([1]German)

Action required:

- Please return all stocks of this batch to DSV Solutions, or the wholesaler/distributor that you purchased it from, for credit.
- Bayer is working to further investigate the source and levels of nitrosamine impurities in Gastrografin/Urografin batches, in order to implement corrective actions to minimise nitrosamine presence.
- Bayer continues the discussions with health authorities and supervisory authorities.
- Bayer encourages the use of alternative contrast agents and therapeutics in the performance of these CT and X-ray procedures, and for patient treatment
- Kindly retain this letter in a prominent position for one month, in case stock is still in transit.

Call for reporting

- Healthcare professionals are urged to report any adverse drug reactions (ADRs) via the Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or App Store. For more information on Med Safety App, please use the following link: https://medsafety.sahpra.org.za/.

- For more information on ADR reporting of the products listed in this letter, please contact the SAHPRA Pharmacovigilance unit at pvqueries@sahpra.org.za or Bayer at pv.sewa@bayer.com.

For further information about this Recall, please contact Bayer at +27 11 921 5911

Yours sincerely
Bayer (Pty) Ltd

Eric Chauke
Regulatory Affairs/
Responsible Pharmacist