NSW Health

Recall and disruption to supply of Gastrografin® and Urografin® contrast agents

SAFETY NOTICE 006/26

Issue date:	6 March 2026
Content reviewed by:	Medicine Shortage Assessment and Management Team Clinical experts – ACI Medical Imaging, Urology and Surgical Networks
Distributed to:	Chief Executives, Directors of Clinical Governance
KEY MESSAGE:	There is a current disruption to the supply of Gastrografin® oral liquid and Urografin® 30% injection ampoules and bottles (both containing amidotrizoate meglumine and sodium amidotrizoate) as a result of a Therapeutic Goods Administration (TGA) Class II recall affecting all formulations/batches of both contrast agents. All supply is to be immediately quarantined in accordance with the advice provided by the TGA, and alternative contrast agents or diagnostic/treatment modalities should be utilised where these agents were previously used.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where Gastrografin® and Urografin® products are stored, prescribed and administered. 2. Ensure all supply of Gastrografin® and Urografin® is immediately quarantined in accordance with the advice provided by the TGA. 3. Undertake a local risk assessment and incorporate the below recommendations to manage this recall and subsequent disruption to supply. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Report any incidents or near-misses associated with this disruption to supply into the local incident management system, for example, ims+.
We recommend you also inform:	Directors, Managers and Staff of: • Medical Imaging, Radiology and Interventional Radiology Departments • Gastroenterology Departments • Urology Departments • Surgical Departments • Medical Services • Nursing and Midwifery Services • Pharmacy Services • All outpatient clinics and day centres Drug and Therapeutics Committees All other relevant clinicians, clinical product managers, departments and committees
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
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Situation

There is a current disruption to the supply of Gastrografin® oral liquid and Urografin® 30% injection ampoules and bottles (both containing amidotrizoate meglumine and sodium amidotrizoate) as a result of a Therapeutic Goods Administration (TGA) Class II recall affecting all formulations and batches of both contrast agents.

The recall issued on 5 March 2026 (TGA reference: RC-2026-RN-00132-1, accessible via TGA Database of Recalls, Product Alerts and Product Corrections) is due to the detection of a nitrosamine impurity at levels exceeding the justified acceptable intake limit.

Background

Gastrografin oral liquid and Urografin 30% injection ampoule and bottle products contain the active ingredients amidotrizoate meglumine and sodium amidotrizoate. They are iodinated contrast agents indicated for use in diagnostic imaging procedures.

- Gastrografin® is indicated for the examination of the gastrointestinal tract. It can be administered orally and as an enema and is primarily indicated in cases in which the use of barium sulfate is unsatisfactory, undesirable or contraindicated. Gastrografin is listed on the NSW Medicines Formulary for off-label use for "*the treatment of meconium ileus or for management of small bowel obstruction in accordance with a DTC approved protocol*".
- Urografin® is indicated for intravenous and retrograde urography, computerised tomography (CT), angiographic procedures, and other contrast studies.

Note: Dyes and diagnostic agents without a therapeutic use are considered non-core pharmacy products and are not listed on the Formulary. The use of these agents for their approved indication (dyes and diagnostic agents for diagnostic purposes) is under local Drug and Therapeutics Committee (DTC) governance processes.

Nitrosamines are chemical compounds that may be present in trace amounts in certain pharmaceuticals. Due to their potential mutagenicity, nitrosamines are classified with the “Cohort of Concern” for DNA-reactive (mutagenic) impurities and are associated with a potential carcinogenic risk. Testing undertaken by Bayer, the sponsor of both agents, identified nitrosamine levels exceeding the acceptable intake limit in most batches tested across all contrast agent formulations containing amidotrizoate meglumine and sodium amidotrizoate.

Although the risk from nitrosamine levels exceeding the acceptable intake limit is considered low, a potential patient safety risk cannot be fully excluded. Administration of a contaminated contrast agent may pose a carcinogenic risk; however, a thorough review of safety information collected by Bayer since these products have been in use shows **no indication** that Gastrografin or Urografin increase the risk of cancer. As a precautionary measure, Bayer is recalling all affected formulations globally.

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Assessment

All Gastrografin and Urografin Australian registered products are affected by the recall and subsequently subject to a disruption to supply. There is **no confirmation** of the expected return to normal supply.

Bayer is the main global supplier of Gastrografin and Urografin. Due to the global nature of this recall, it is unlikely that internationally registered alternatives will be available via the TGA's Special Access Scheme (SAS), however investigations are ongoing. If alternatives were to become available, this would either be under SAS arrangements or Section 19A (S19A) of the *Therapeutic Goods Act 1989* after publication of this Safety Notice. Please refer to the TGA S19A approvals database.

Alternative Australian registered contrast agents or diagnostic/treatment modalities will need to be considered where clinically appropriate.

Recommendations

Recall actions

- Ensure all stock of Gastrografin and Urografin products are **immediately identified and quarantined** to prevent further use.
- Take extra care to ensure that all potential areas for the storage of the affected stock have been determined and checked, including but not limited to:
  - medication rooms
  - after hours drug cupboards
  - procedure rooms/trolleys.
- Refer to the TGA market action (recall notice) circulated to local Recall coordinators and Directors of Clinical Governance on Thursday 5 March 2026 for further information and instructions on returning affected stock to the sponsor, Bayer.

Alternative contrast agents

- Where Gastrografin or Urografin would have been utilised, alternative contrast agents or alternative diagnostic/treatment modalities need to be considered where clinically appropriate.
- Gastrografin is a high-density, iodinated contrast medium which contains a high concentration of iodine (**370 mg/mL**). The density of alternatives should be considered – Omnipaque™ 350 for example, contains a comparable concentration of iodine (**350 mg/mL**). Selection of an alternative contrast agent or alternative diagnostic/treatment modalities should be undertaken in consultation with a radiologist and/or the relevant specialist(s).
- Alternative contrast agents that may be considered include, but is not limited, to:
  - iohexol (Omnipaque) – see note about density above
  - barium sulfate (READI-CAT 2) – accessible via Regional Health
  - sodium amidotrizoate (Ioscan)
  - iopamidol (Isovue)
  - iodixanol (Visipaque)
  - ioversol (Optiray).
- Clinicians are advised that supply of these alternatives is available at the time of publication.

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- Advice should be sought from the relevant specialist(s) surrounding dosing and dilution requirements.
- Clinicians are advised that for therapeutic (osmotic) uses of Gastrografin, the above alternatives may not be suitable as they are non-ionic, low-osmolar, and do not provide a comparable osmotic effect. Clinicians should seek advice from the relevant specialist(s) regarding the use of alternatives.

Stock management

- Where alternative contrast agents are required, ensure that supply is used judiciously, in consideration of the potential flow on effects of the disruption to supply of Gastrografin and Urografin. The Clinical Excellence Commission and HealthShare NSW are working closely to establish the demand for the alternative products, for communication to the relevant sponsors, to ensure continuity of supply.
- Facilities should develop a local plan to manage the supply of alternative agents that includes (but is not limited to):
    - assessing current stock holdings, usage and clinical appropriateness of the individual agent(s)
    - ensure orders are in place for alternatives that are relative to expected usage.
- Should SAS/S19A alternatives become available, it is recommended that:
    - Sites have accounts set up with the relevant suppliers to enable timely access to these alternatives.
    - Supplier and product details are set up in Oracle to allow for smooth ordering and receipting of products that may not have been held before.
    - Sites consider the lead time to process orders and are proactive in placing orders. This may include placing back orders with suppliers. As products are being imported from international locations, lead times may be variable and considerable (at times up to 14 business days).
- Any concerns regarding ongoing supply of alternative agents are to be escalated to CEC-MedicationSafety@health.nsw.gov.au.