NSW Health

Disruption to supply – lidocaine (lignocaine) 1% (50 mg/5 mL) solution for injection

SAFETY NOTICE 015/25

Issue date:	19 June 2025
Content reviewed by:	Medication Shortage Assessment and Management Team Medication Safety Expert Advisory Committee ACI Cardiac Network Intensive Care NSW
Distributed to:	Chief Executives; Directors of Clinical Governance
KEY MESSAGE:	NSW Health facilities are informed of the current disruption to the supply of lidocaine 1% (50 mg/5 mL) solution for injection from Lumacina®, Baxter® and Xylocaine®, the availability of an alternative Australian-registered product, lidocaine Noridem® 1%, and the associated safety considerations.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where lidocaine 1% solution for injection is held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendations to manage the disruption to supply. 3. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+.
We recommend you also inform:	Directors, Managers and Staff of: • Emergency Departments • Intensive Care Units • Anaesthetics and Recovery Departments • Interventional Radiology • Medical imaging • Cardiology Services • Medical Services • Nursing and Midwifery Services • Pharmacy Services Drug and Therapeutics Committees All other relevant clinicians, departments and committee
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	December 2025

Contact: Clinical Excellence Commission
02 9269 5500
cec-medicationsafety@health.nsw.gov.au

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Situation

There is a current disruption to the supply of lidocaine 1% (50 mg/5 mL) solution for injection products due to manufacturing issues and increases in demand until at least July 2025. Three of the four Australian registered brands are affected, namely LumaCina®, Baxter® and Xylocaine®. Return to supply dates vary by brand. Limited supply may continue to be available over the coming weeks (for example, limited supply of available Baxter lidocaine 1% has been allocated by HealthShare NSW to sites with the greatest need).

Lidocaine Noridem® 1% remains available, however is not approved for the treatment or prophylaxis of life-threatening ventricular arrhythmias and is labelled as '*not for systemic intravenous use*' (see Table 1). **Note** – Xylocaine® carries the same precaution.

At the time of publication, lidocaine 2% (100 mg/5 mL) solution for injection remains available.

Background

Lidocaine is an amide type local anaesthetic and class 1 membrane stabilising antiarrhythmic. It is indicated for:

- local or regional anaesthesia by nerve block, infiltration, injection, caudal or other epidural blocks (all brands)
- systemic administration for the treatment or prophylaxis of life-threatening ventricular arrhythmias including those associated with myocardial infarction, general anaesthesia in patients predisposed to ventricular arrhythmias, digitalis intoxication, or following resuscitation from cardiac arrest (specific brands only)
- pain management under specialist advice when used systemically via the IV route (off-label use).

Assessment

LumaCina and Baxter lidocaine 1% solution for injection ampoules are the only products listed on the Australian Register of Therapeutic Goods (ARTG) that are approved for systemic intravenous use. The Xylocaine or Noridem lidocaine 1% products are not approved for this use, and their packaging features the text '*not for systemic intravenous use*'.

Xylocard 10% (lidocaine 10%) remains available, and is approved and marketed for IV administration for the treatment and prophylaxis of life-threatening ventricular arrhythmias. However, due to its higher concentration, this product should only be used as an alternative to lidocaine 1% or 2% once appropriately diluted. Instructions for dilution, as per the Australian Injectable Drugs Handbook:

- Dilute in a compatible fluid to a usual concentration of 1 to 2 mg/mL. Concentrations up to 8 mg/mL can be used in fluid-restricted patients.
- Practical example: Use the 10% solution (Xylocard) and dilute 500 mg (5 mL) in 500 mL of compatible fluid to make a concentration of 1 mg/mL.

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Recommendations

To effectively manage the disruption to the supply of Lumacina, Baxter and Xylocaine lidocaine 1% (50 mg/5 mL), it is recommended that NSW Health services:

- Reserve remaining supply of the Lumacina and Baxter lidocaine 1% brand for clinical indications where systemic intravenous administration is required (including treatment or prophylaxis of life-threatening ventricular arrhythmias).
- Undertake a facility-wide review of stock holdings and recall excessive stock of the Lumacina and Baxter lidocaine 1% from clinical areas where an alternative brand (Xylocaine or Lidocaine Noridem) is appropriate for use. For example, in areas where lidocaine is required for local and regional anaesthesia.
    - Clinical requirements must be carefully assessed to ensure adequate stock remains in clinical areas for the treatment of life-threatening events.
    - Where possible, lidocaine 2% should be utilised (for example, for wound management) to help preserve the 1% formulation. Ensure accurate dose calculation and verification to account for the difference in concentration.
- Review local protocols and procedures to ensure the appropriate lidocaine product is being used (based on the indication and required route of administration).
- Communicate with clinicians regarding the need to switch to an alternative brand (such as Xylocaine or Lidocaine Noridem) for local or regional anaesthesia and to reserve Lumacina and Baxter supply for systemic intravenous use.

In the event of a complete disruption to the supply of the Lumacina and Baxter products, the following may be considered:

- Use of Lidocaine Noridem 1% for systemic intravenous administration (contrary to the Australian Product Information). While not approved for use in this way by the TGA, the product is approved internationally for this indication, and the product does not contain any excipients which preclude systemic intravenous use.
    - Appropriate communication, education and **over-labelling** will be required to minimise confusion due to the product labelling, particularly where this product is stored in emergency trolleys/kits.
- Use of Xylocard 10% (lidocaine 10%) as an alternative after appropriate dilution.

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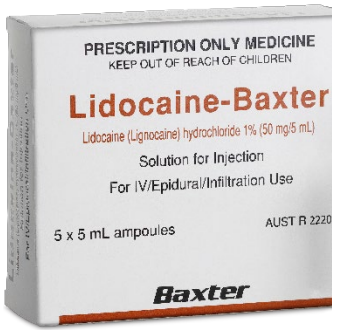
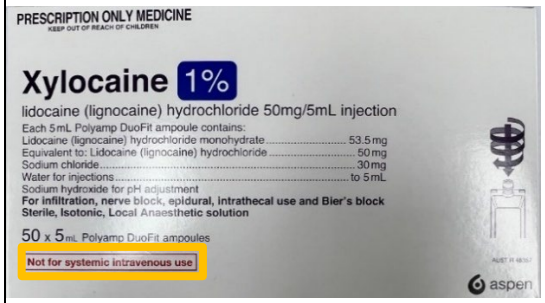
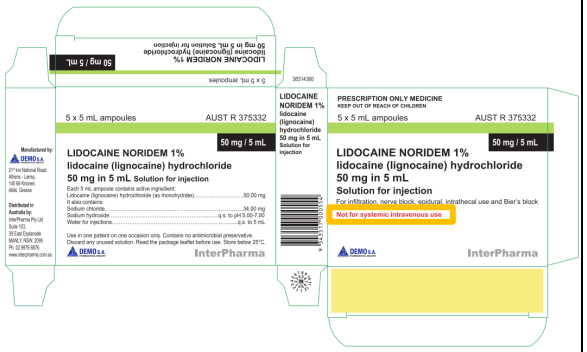
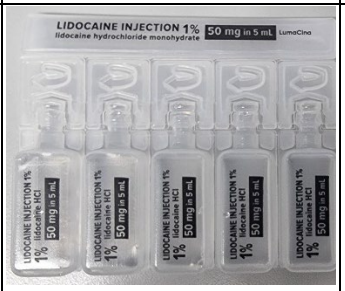
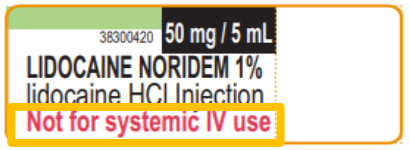
Table 1: Comparison of lidocaine 1% (50 mg/5 mL) solution for injection products

Product	LumaCina lidocaine (ARTG 49296)	Lidocaine Baxter (ARTG 222077)	Xylocaine (ARTG (48357)	Lidocaine Noridem (ARTG ID 375332)
Approved by TGA for systemic intravenous use	Yes	Yes	No	No
Outer packaging appearance/ artwork				
Single item appearance/ artwork				

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