Safety Notice 023/23

Issue date
23 August 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Emergency Departments
- Intensive Care Units
- Anaesthetics and Recovery Departments
- Medical imaging
- Medical Services
- Nursing/Midwifery Services
- Pharmacy Services

Drug & Therapeutic Committees

All other relevant clinicians and clinical departments where lidocaine solution for injection is prescribed, stored, and administered.

Expert Reference Group
Content reviewed by:
Medicine Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee
ACI Anaesthesia and Perioperative Care Network

Clinical Excellence Commission
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Review date
January 2024

Disruption to supply – Lidocaine (lignocaine) 1% (50 mg/5 mL) and 2% (100 mg/5 mL) solution for injection (Pfizer and Baxter)

Situation

There is a current disruption to the supply of lidocaine 50 mg/5 mL (Pfizer® and Baxter® lidocaine 1%) and 100 mg/5 mL (Pfizer and Baxter lidocaine 2%) solution for injection due to changes in commercial viability. Limited supply may continue to be available.

Alternative brands, for example Xylocaine®, remain available however are not approved for the treatment or prophylaxis of life-threatening ventricular arrhythmias and are labelled as '*not for systemic intravenous use*' (see Figure 1 on next page). The Product Information for Xylocaine® indicates it is acceptable via intravenous route for regional anaesthesia only with the Bier's block technique after further dilution to a concentration of 5 mg/mL (0.5%) to avoid systemic spread and minimise the risk of toxicity.

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

The Pfizer and Baxter lidocaine 1% and 2% are the only products registered on the Australian Register of Therapeutic Goods that are approved for systemic intravenous use and do not have '*not for systemic intravenous use*' on their packaging.

Xylocard 10% (lidocaine 10%) 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 is **NOT** appropriate or safe as an alternative to lidocaine 1% or 2% without further dilution.

Recommendations

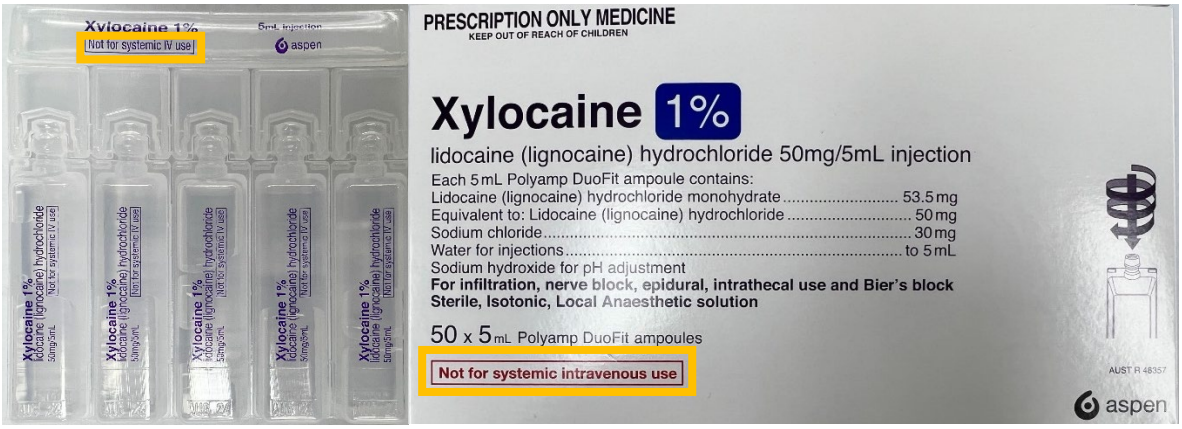
To effectively manage the disruption to the supply of lidocaine 1% and 2% Pfizer and Baxter stock, it is recommended that:

- Remaining stock of the Pfizer and Baxter brand is reserved for clinical indications where systemic intravenous administration is required (including prophylaxis and treatment of severe life-threatening tachycardia).
- A facility-wide review of stock holdings should be undertaken, and excess stock of the Pfizer and Baxter brands recalled from clinical areas where an alternative brand (e.g. Xylocaine) is appropriate for use. For example, in anaesthetic and recovery departments where lidocaine is required for local and regional anaesthesia, the alternative brands should be used.
- Clinical requirements must be carefully assessed to ensure adequate stock remains in clinical areas for the treatment of life-threatening events.
- Review local protocols and procedures to ensure the appropriate lidocaine product is being used (based on the indication and required route of administration).

Recommendations cont.

- Communicate with clinicians regarding the need to switch to an alternative brand (e.g. Xylocaine) for local or regional anaesthesia and to reserve Pfizer and Baxter supply for systemic intravenous use.
- In the event of a complete disruption to the supply of the Pfizer and Baxter products, local endorsement will be required by the Drug and Therapeutics Committee for the use of an alternative brand (such as Xylocaine) for systemic intravenous administration. It should be noted that this is **off-label use** and contrary to the TGA approved Product Information and product labelling. Appropriate communication, education and overlabelling will be required to minimise confusion due to the product labelling.

Figure 1. Xylocaine 1% ampoules and outer packaging which features *'not for systemic intravenous (IV) use'* labelling.



Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where lidocaine solution for injection is stocked, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above 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+.
5. Confirm receipt and distribution of this Safety Notice **within 72 hours** to CEC-MedicationSafety@health.nsw.gov.au