

Issue date
7 June 2022

Distributed to:
Chief Executives
Directors of Clinical Governance

Action required by:
Directors of Clinical Governance

We recommend you also inform:

- Directors of:
- Anaesthetics
 - Intensive Care Units
 - Medical Services
 - Nursing and Midwifery
 - Pharmacy
- Operating Theatre staff
Medical staff
Nursing staff
Pharmacists
Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Clinical Excellence Commission
Medication Safety Expert Advisory Committee
ACI Surgical Services Taskforce

Clinical Excellence Commission

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Review date
December 2022

'Sterile Theatre Pack' formulations of lignocaine (lidocaine) with adrenaline (epinephrine) and bupivacaine with adrenaline (epinephrine) injection disruption to supply – **UPDATED**

This is an update of SN004/22 that was released in May 2022. New information is highlighted in yellow.

Situation

Due to supply disruptions to 'Sterile Theatre Pack' formulations of lignocaine (lidocaine) with adrenaline (epinephrine) and bupivacaine with adrenaline (epinephrine) injections, alternative versions of these products will be made available. These products are non-autoclaved, will not be individually wrapped in secondary packaging, and should not be placed directly into the sterile field in theatre.

Background

There is a current disruption to the following products:

Bupivacaine with adrenaline (epinephrine)

- Marcain 0.25% with adrenaline 1:400,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 125878
- **Marcain 0.5% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 48329**

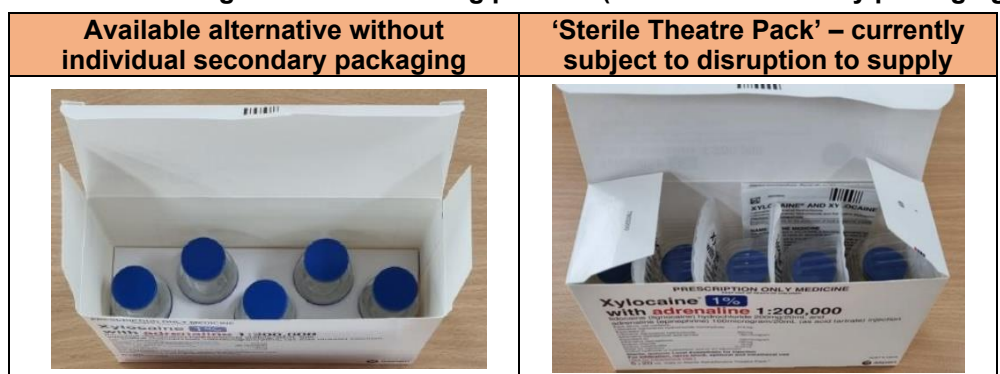
Lignocaine (lidocaine) with adrenaline (epinephrine)

- Xylocaine 2% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12021
- Xylocaine 1% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12015
- Xylocaine 0.5% with adrenaline 1:200,000 injection vial 20 mL 'Sterile Theatre Pack' – ARTG 12008

Additional 'Sterile Theatre Pack' products may be affected in the future and the following advice should be applied to all alternatives without individual secondary packaging.

The disruption is due to a change in the local autoclaving site for these products. The set-up of the new site, and anticipated return to normal supply for the abovementioned products, has been delayed until at least **September 2022**. In the interim, the drug sponsor has gained TGA approval to supply a non-autoclaved version of these products. These products will not be individually wrapped in secondary packaging and will not be termed 'Sterile Theatre Pack' however the contents of the vials are sterile.

Alternative products may also be available under section 19A of the Therapeutic Goods Act 1989 – see [database](#). **The safety concerns on the next page apply to any product that has not undergone the autoclaving process (i.e. not in secondary packaging).**



Safety concerns

The alternative non-autoclaved products will not be individually wrapped in secondary packaging and **should not be** placed directly into the sterile field in theatre. Existing procedures for handling and administering of non-autoclaved products are to be used when handling these alternative products. Please ensure all staff are aware of this practice change for these alternative products prior to use.

Note – the autoclaving process is designed to sterilise the external surfaces of the vial but has no impact on the solution inside the vial, which is already sterile.

Required actions for the Local Health Districts/Networks

1. Forward this Safety Notice to relevant clinicians, clinical departments and Drug and Therapeutics/Medication Safety Committees for action.
2. Undertake a local risk assessment and develop strategies to mitigate the risks associated with the use of the non-autoclaved alternatives e.g., through the application of cautionary labels on product packaging, use of shelf talkers.
3. Ensure staff members in clinical areas administering these products are made aware of these risks.
4. Ensure a system is in place to document and review actions taken in response to this Safety Notice and any incidents involving these products.
5. Confirm receipt and distribution of the updated notice to CEC-MedicationSafety@health.nsw.gov.au by **COB Wednesday 8 June 2022**.