

Medication Safety Notice

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Issued by Medicines and Technology Policy and Programs, SA Health

www.sahealth.sa.gov.au/medicationsafety



A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

- Heads of Anaesthesia
- Heads of Intensive Care Departments
- Pharmacy Directors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Drug and Therapeutics Committees
- Medication Safety Committees
- Safety and Quality Units
- Clinical Governance

Contact details:

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TGA lifts propofol quarantine and highlights the importance of good aseptic technique

Provide and Sandoz Propofol 1% emulsion for injection were quarantined from use as a precaution in early May 2014 pending the Therapeutic Goods Administration (TGA) investigation into potential contamination with *Ralstonia* species. Eight cases of bacteraemia were reported, including three from South Australian hospitals.

Based on the balance of the information now available, the TGA is confident that supply restrictions are not necessary for Provide 1%, Provide MCT-LCT 1% or Propofol Sandoz 1% emulsion for injection products.

This includes batches A030906 and A030907 of Provide MCT-LCT 1% emulsion for injection which were the batches quarantined following the initial notification of a potential problem.

While the investigations into the possible causes are continuing, the TGA is satisfied that the contents of the propofol emulsion vials from these batches are not contaminated.

Aseptic technique important

Health practitioners should be aware that the outer surface of injection vials, including the outer surface of the rubber stopper and the inner surface of the vial lid or cap, are not required to be sterile and may not be free from microbial contamination.

Strict aseptic technique must be followed when preparing and administering injections to patients. This includes wiping the outer surface of the rubber stopper with a suitable disinfectant swab and allowing it to dry before inserting any device into the vial.

Product information supplied by the product sponsors, Claris and Sandoz, includes further information about the importance of aseptic handling to minimise the opportunity for infections in patients.



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Action required by health professionals

Health practitioners should:

1. be aware that the outer surface of the rubber stopper and the inner surface of injection vial lid or cap are not sterile
2. ensure proper aseptic technique is strictly followed when preparing and administering injections, including
 - a. wiping the outer surface of the rubber stopper and the injection site with a suitable disinfectant swab, and
 - b. allow it to dry before inserting any device into the vial

Action required by SA Health services

Health services should:

1. ensure systems are in place to ensure staff are aware and comply with strict aseptic technique when preparing and administering injections
2. remove the quarantine precautions on propofol products.

References:

[TGA Notice 7 July 2014 Propofol release from Quarantine](#)

[MIMS Provive 1% Package Insert](#)

[MIMS Propofol 1% Sandoz Package Insert](#)

[MIMS Provive 1% MCT-LCT Package Insert](#)



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