Safety Notice 002/19

Morphine sulfate 30 mg/mL injection – disruption to supply

15 February 2019

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of Anaesthetics Departments
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery
- Drug and Therapeutics Committee

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer, MoH
- Chief Pharmacists Unit, MoH
- Director Patient Safety, CEC

Clinical Excellence Commission

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http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

February 2020

Background

There is a current shortage of DBL preservative-free morphine sulfate 30 mg/mL injection. This is the only morphine 30 mg/mL injection registered in Australia. Stock is estimated to return 30 May 2019. There is availability of the DBL preservative free morphine sulfate 5 mg/mL, 10 mg/mL and 15 mg/mL strengths.

The DBL preservative-free morphine sulfate 30 mg/mL injection has **not** been approved for use via the intrathecal or epidural route, and lists only intravenous, intramuscular and subcutaneous routes on its packaging and in the Product Information. However, it is understood that there is some 'off-label' use via the epidural and intrathecal route.

The UK registered product *Morphine Sulfate Injection BP 30 mg in 1 mL ampoules* (accessible via Link Medical Products P/L) has been approved for limited supply under an exemption granted by the Therapeutic Good Administration under section 19A of the Therapeutic Goods Act 1989.

The UK registered product (*Figure 1*) has a critical formulation difference from the Australian registered DBL product, it contains the preservative sodium metabisulfite and therefore **must not be used for epidural or intrathecal use**.

Medicines containing preservatives if administered via the epidural or intrathecal route, can be neurotoxic and may cause spinal cord injury. The UK product **must only** be administered subcutaneously, intravenously or intramuscularly.

Figure 1. Packaging of UK registered product Morphine Sulfate Injection BP 30 mg in 1 mL with warning in red.

Hospitals should assess usage of preservative-free morphine sulfate 30 mg/mL injection for intrathecal and/or epidural use across their facility and implement local plans to manage the shortage.

Recommended actions by Local Health Districts/Networks

1. Distribute this notice to relevant staff at each facility.
2. Plan and implement strategies to manage the substitution at a local level by the Drug and Therapeutics/Medication Safety Committee.
3. Consider reserving remaining stock of DBL preservative-free morphine sulfate 30 mg/mL ampoules for patients where the UK product containing preservative, or lower strengths of the preservative-free product, cannot be used e.g. for intrathecal pumps.
4. Review storage of morphine products – if products must be co-located, separate the preservative-free morphine sulfate 30 mg/mL from the UK product containing preservative within the S8 drug safe/cupboard.
5. Retain morphine sulfate ampoules in their original packaging
6. Use separate pages of the drug register for preservative-free morphine 30 mg/mL injection and the UK preservative containing product.
7. Ensure a system is in place to document actions taken.
8. Report any incidents associated with use of morphine injection into the Incident Information Management System (IIMS).
9. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au