



Safety Notice 001/12

Morphine sulfate injection 10mg/mL ampoules supply changes and toxicity issues

17 December 2012

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Drug and Therapeutics Committees

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

We recommend you also inform:

- Directors of Pharmacy
- Theatre Managers
- Anaesthetics Heads of Departments
- Directors of Nursing

Expert Reference Group

Content reviewed by:

- Clinical Excellence Commission
- Pharmaceutical Services
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

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<http://www.health.nsw.gov.au/quality/sabs>

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<http://internal.health.nsw.gov.au/quality/sabs/>

Background

There will be a supply shortage of DBL™ preservative-free morphine sulfate injection, 10mg/mL ampoules from December 2012/January 2013 for approximately 6 months. In the interim Wockhardt™ morphine sulfate injection 10mg/mL will be available.

These two products have critical differences. Wockhardt™ morphine sulfate injection 10mg/mL contains the preservative sodium metabisulfite. **If Wockhardt™ morphine sulfate is administered by the intrathecal or epidural route, it may cause significant patient harm.** Wockhardt™ morphine sulfate injection 10mg/mL **must only** be administered subcutaneously, intravenously or intramuscularly.

DBL™ preservative-free morphine sulfate injection is administered via the intrathecal and/or epidural routes in many facilities across NSW and is an important clinical option in pain management. Staff must be advised that Wockhardt™ morphine sulfate injection 10mg/mL is not a suitable alternative for preservative-free morphine in these clinical situations. Inappropriate substitution of Wockhardt™ morphine sulfate injection containing the preservative sodium metabisulfite, may result in serious patient harm.

The TGA, together with the product sponsor, have prepared posters and additional labelling for the product boxes, to alert health care practitioners to the differences between the DBL™ and Wockhardt™ products. These materials and up to date information about supply issues can be obtained from <http://www.tga.gov.au/hp/information-medicines-morphine-sulfate-products.htm>.

Alternative preservative-free morphine sulfate products are available through local manufacturers and can be administered via epidural or intrathecal routes. Details of these products can be obtained from contract902@hss.health.nsw.gov.au.

Implementing the actions in this Safety Notice will reduce the risk of intrathecal or epidural injection of Wockhardt™ morphine sulfate.

Local Health Districts / Networks Should

- Alert practitioners to the impending change in supply of morphine sulfate injection 10mg/mL, highlighting the differences between the DBL™ and Wockhardt™ products.
 - Disseminate this notice.
 - Place posters supplied with Wockhardt™ morphine sulfate products in a prominent position.
 - Retain Wockhardt™ morphine sulfate products in their original packaging wherever possible.
- Ensure that adequate stocks of preservative-free morphine are obtained for intrathecal and epidural use.
 - Consider reserving remaining stocks of DBL™ preservative-free morphine sulfate injection 10mg/mL for use exclusively in procedural areas where intrathecal and/or epidural morphine is administered.
 - Consider procurement of other preservative-free morphine injections.
 - Stock only preservative-free morphine injections in procedural areas whenever possible.
- Review storage of morphine products
 - Where products must be co-located, separate preservative-free morphine and Wockhardt™ morphine sulphate injection 10mg/mL products within the S8 drug safe/cupboard.
- Use separate pages of the drug register for preservative-free morphine and Wockhardt™ morphine sulphate injection 10mg/mL products.
 - Label appropriate pages of the drug register with stickers provided to clearly indicate the presence of a preservative in Wockhardt™ morphine sulphate injection 10mg/mL.

For Further Information

For updated information about product availability see <http://www.tga.gov.au/hp/information-medicines-morphine-sulfate-products.htm>.

Suggested actions by Local Health Districts/Networks

- Determine clinical areas where intrathecal and/or epidural morphine is used
- Ensure that action has been taken to maintain supply of preservative-free morphine to these areas
- Consider the recommendations provided to limit the possibility of intrathecal or epidural administration of preservative-containing morphine (Wockhardt™ morphine) clearly documenting actions taken.