Safety Notice 001/18

Midazolam injection 5 mg/5 mL shortage and risk of error

5 January 2018

Distributed to:

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

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Anaesthetics
- Directors of Emergency Departments
- Directors of Intensive Care
- Directors of Medical Services
- Directors of Palliative Care
- Directors of Pharmacy
- Operating Theatre Managers
- Directors of Nursing and Midwifery

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer, MoH

Clinical Excellence Commission

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

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

Review date

April 2018

Background

A disruption to the supply of Pfizer midazolam injection 5 mg/5 mL ampoules has occurred. This has impacted demand and availability of alternate brands of midazolam injection 5 mg/5 mL ampoules used in NSW hospitals. Supply of Pfizer midazolam injection 5 mg/5 mL is expected to return to normal in March 2018. Supply of other brands of this product may be sporadic during this time.

Midazolam is a short-acting injectable benzodiapine used for sedation in a range of settings. Indications include conscious sedation prior to short surgical, diagnostic, therapeutic, or endoscopic procedures, anaesthesia induction, sedation in intensive care, and pre-operative sedation. Adverse effects include respiratory depression and apnoea, and rarely cardiac and/or respiratory arrest. Midazolam is a high risk medicine; refer to the NSW High-Risk Medicines Management Policy (PD2015_029) for relevant Standards relating to its use.

Implications

To manage the disruption to supply, midazolam injection **5 mg/1 mL** is available, however, **there is a risk of medication error due to the higher concentration of this product**, particular when used in clinical settings by staff that are not familiar with midazolam injection 5 mg/1 mL.

Administration of the same volume of midazolam 5 mg/1 mL to 5 mg/5 mL injection will result in a five-fold error and overdose.

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all stakeholders and all clinical departments.
2. Assess the current status of midazolam injection 5 mg/5 mL preparations available in each facility; ensuring location of all stock is identified.
3. Undertake a risk assessment at a local level with the Drug and Therapeutics/Medication Safety Committee to determine whether use of midazolam 5 mg/1 mL in the interim is appropriate.
4. Plan and implement strategies to manage the substitution at a local level by the Drug and Therapeutics/Medication Safety Committee.
5. Ensure a system is in place to document actions taken.
6. Report any incidents associated with use of midazolam into the Incident Information Management System (IIMS).