



# 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**

Tel. 02 9269 5500  
Fax. 02 9269 5599

Email:  
[CEC-Quality@health.nsw.gov.au](mailto:CEC-Quality@health.nsw.gov.au)

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 benzodiazepine 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).