Safety Notice 006/17

Dantrium (dantrolene sodium) Powder for Injection vials - Disruption to Supply

5 April 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Anaesthetics Department Heads
- All anaesthetic staff
- Operating Theatre Managers
- Directors of Surgery
- Directors of Nursing and Midwifery
- Directors of Pharmacy
- Directors of Medical Services
- Directors of Emergency Departments
- After Hours Managers
- Drug and Therapeutics Committees and subcommittees

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission
- ACI Anaesthesia Perioperative Care Network

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 9269 5599

Email:
Cec-quality@health.nsw.gov.au

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

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

Review date

December 2017

Background

An out of stock notification has been received for Dantrium (dantrolene sodium) Powder for Injection from the drug sponsor, Pfizer. This is due to an unexpected manufacturing delay. This is the only supply of intravenous dantrolene sodium currently marketed in Australia. The disruption to supply is predicted to continue until 31 December 2017.
The affected product is:

ARTG No.	ARTG Label	Sponsor	Contains
14435	DANTRIUM dantrolene sodium hemiheptahydrate 20 mg powder for injection vial	Pfizer Australia Pty Ltd	dantrolene sodium

To ensure ongoing availability for patient care, hospitals may be required to purchase and use overseas supply of dantrolene sodium products through the Special Access Scheme. It is anticipated that stock will become available through the Section 19a process within the next 2 weeks.

Intravenous dantrolene sodium is a muscle relaxant acting specifically on skeletal muscle. It is indicated, along with appropriate supportive measures, for the management of malignant hyperthermia. It is a lifesaving drug that must be administered immediately to a patient with symptoms of malignant hyperthermia. This condition may occur when a susceptible patient is given a volatile anaesthetic or suxamethonium. The estimated incidence is 1:100,000 administered anaesthetics.

There are no medications that can be used in place of intravenous dantrolene sodium for malignant hyperthermia. Where the product is used within several weeks of expiry, any risk is likely to be limited to a potential reduction in the amount of active ingredient.

Further Information

For details of supply options for Special Access Scheme (SAS) products, email: HSNSW-contract902@health.nsw.gov.au.

To manage the current shortage, Local Health Districts/Networks should:

1. Distribute this safety notice to all stakeholders and clinical departments affected by the shortage of Dantrium (dantrolene sodium) Powder for Injection vials.
2. Develop a local plan to manage activities during the supply shortage, including:
   a. an assessment of the current supply and date of intravenous dantrolene sodium in each facility;
   b. communication regarding the availability and location of intravenous dantrolene sodium to all staff involved in administering or caring for patients receiving general anaesthesia;
   c. management of patients with suggestive or known history or family history of malignant hyperthermia as per the following recommendations:
      - defer elective surgery until sufficient stock is available
      - carry out emergency surgery using a non-triggering anaesthetic with informed patient consent
      - further details on the management of MH susceptible patients are available from: www.anzca.edu.au/resources/endorsed-guidelines; and
   d. immediately ordering supply of intravenous dantrolene sodium products through the Special Access Scheme if there is insufficient stock to meet minimum levels, noting the approaching Easter holiday period.
3. Retain stock of dantrolene sodium with expiry date 31 March 2017 until it can be replaced by in-date stock. Given the lifesaving, emergency nature of the treatment, rarity of the event, recency of product expiry, and the fact that the dose is titrated to response, it is reasonable to consider using the recently expired stock until new stock is available. Drug and Therapeutics Committees should determine local procedures.
4. Inform clinicians, stakeholders and clinical departments when supply of intravenous dantrolene sodium is reinstated.
5. Ensure a system is in place to document actions taken.