Issue date
9 May 2023

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:
Directors, Managers and Staff of:
- Surgery, Anaesthetics
- Intensive Care Units
- Emergency
- NSW Ambulance
- Medical
- Nursing/Midwifery
- Pharmacy

Drug & Therapeutics Committees
All other relevant clinicians and clinical departments where these products are prescribed, stored and administered.

Expert Reference Group
- Medicines Shortage Assessment and Management Team
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

Review date
October 2023

Discontinuation of thiopental sodium (Pentothal®) 500 mg vial for injection

Situation

The Australian registered medicine thiopental sodium (Pentothal) 500 mg vial for injection (AUST R: 73505) will be discontinued on 1 August 2023. The sponsor has advised that there will be a reduction in supply of this product until all stock is exhausted.

An alternative product, thiopental sodium (Omegapharm) 470 mg (ARTG – 209478) is available. Clinicians need to be aware of specific safety considerations due to the different strength of this alternative product.

Background

Thiopental sodium is a fast-onset, ultra-short-acting barbiturate-type central nervous system depressant, with hypnotic, anaesthetic and anticonvulsant properties. It's main therapeutic uses include:

- Sole anaesthetic agent for brief surgical procedures.
- Preferred sole anaesthetic agent in electroconvulsive therapy (ECT).
- Induction of general anaesthesia, including emergency procedures such as caesarean section or rapid sequence intubation.
- Burst suppression for status epilepticus or raised intracranial pressure (ICP) in traumatic brain injury.

Assessment

During previous disruptions to the supply of Pentothal 500 mg (most recently in June 2022), the Omegapharm 470 mg product has been utilised in NSW Health facilities. Clinicians need to be aware that the Omegapharm 470 mg product has different dilution and dose calculation requirements compared to the Pentothal 500 mg product. Incorrect reconstitution of the Omegapharm product may result in inaccurate doses being administered to the patient and have significant implications on patient safety. See **Table 1** on next page for product comparison.

Clinical Recommendations

- The current status of thiopental sodium availability in each facility should be assessed, ensuring all locations of stock are identified. Orders for the Omegapharm 470 mg product should be placed by Pharmacy Departments in advance to ensure the timely receipt and ongoing supply of thiopental.
- Actions to prepare for the safe transition to the Omegapharm 470 mg product are to be implemented with liaison between representatives from the local Pharmacy Departments, Drug and Therapeutic Committees and relevant clinicians.

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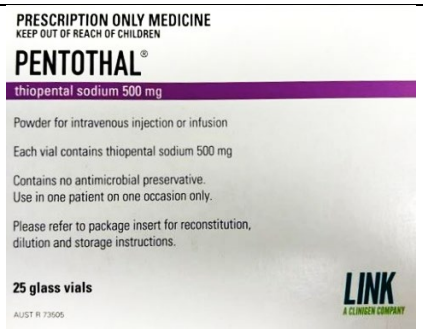
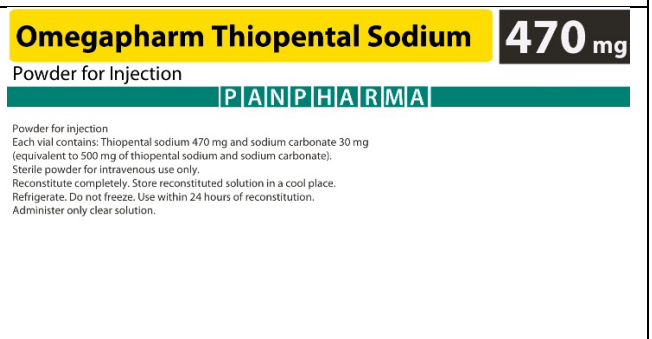
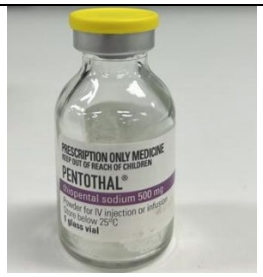
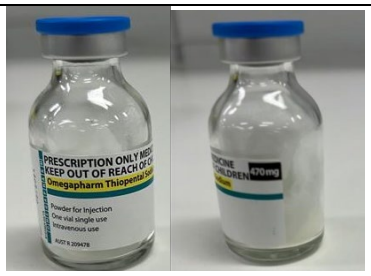
- Clinicians should be made aware of the change in product and provided education regarding the different strength, dilution and dose calculation requirements of the Omegapharm 470 mg product.
- Pharmacy departments may consider applying additional labels to the Omegapharm 470 mg product to alert clinicians of the change in product and its different strength and dilution requirements.
- Governance committees should liaise with local eMeds/ICT teams to update configurations (e.g., order sentences, product catalogues) in eMM systems to reflect the Omegapharm 470 mg product.
- Drug registers and automated dispensing cabinets (ADCs) should be reviewed and updated to include the Omegapharm 470 mg product and reflect appropriate stock counts.
- Clinical guidelines and protocols that include thiopental sodium should be reviewed and updated to reflect the different strength and dilution requirements of the Omegapharm 470 mg product.

Table 1. Comparison – Pentothal 500 mg and Omegapharm 470 mg.

Product	Thiopental sodium 500 mg (Pentothal)	Thiopental sodium 470 mg (Omegapharm)
Active ingredient	Thiopental sodium	Thiopental sodium
Form	Powder, requires reconstitution for injection	Powder, requires reconstitution for injection
Strength	500 mg	470 mg
Reconstitution requirements	Reconstitute the vial with **20 mL** of compatible diluent to make a concentration of 25 mg/mL.	Reconstitute the vial with **18.8 mL** of compatible diluent to make a concentration of 25 mg/mL. **Please note:** Multiple syringes are required to accurately measure an 18.8 mL volume of diluent (e.g. 1 x 20 mL syringe plus 1 x 1 mL syringe).
Excipients	Nil	Nil
Storage	Store below 25°C	Store below 25°C
Outer packaging artwork		
Ampoule appearance		

See Product Information for Pentothal 500 mg product and Omegapharm 470 mg product, and the Australian Injectable Drug Handbook for more information.

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Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where thiopental sodium is prescribed, stored and administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment, and develop strategies to manage the discontinuation of thiopental sodium (Pentothal) which incorporates the recommendations provided in this Safety Notice.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Report any incidents associated with this discontinuation and the introduction of the Omegapharm 470 mg product into the local incident management system e.g., ims+.
5. Confirm receipt and distribution of this Safety Notice **within 72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.