Issue date
3 April 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 Departments
- 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 Content reviewed by:
Medicines Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
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Intranet

Review date
September 2023

Disruption to supply: Suxamethonium chloride (Juno) 100 mg/2 mL injection

Situation

The Australian registered medicine suxamethonium chloride (Juno) 100 mg/2 mL injection (AUST R: 320687) is currently unavailable due to manufacturing issues.

An alternative product suxamethonium chloride solution for injection 100 mg/2 mL (Mercury Pharma) has been approved for supply under Section 19A (S19A) of the Therapeutic Goods Act. It is expected to arrive in Australia during the week commencing 3 April 2023. **Some NSW Health facilities may experience a complete disruption to supply or have minimal stock on hand if availability of the S19A alternative is delayed.**

Background

- Suxamethonium is a depolarising-type neuromuscular blocking agent (NMBA) that has a rapid onset and a short duration of action. It is indicated for skeletal muscle relaxation in anaesthesia where brief paralysis is required.
- NMBAs are considered high-risk medicines because inadvertent use in patients without the availability of medical staff skilled in airway support can lead to respiratory arrest, permanent harm, or death.
- A Neuromuscular Blocking Agent Standard exists as part of the NSW Health Policy Directive *High-Risk Medicines Management* PD2020_045.

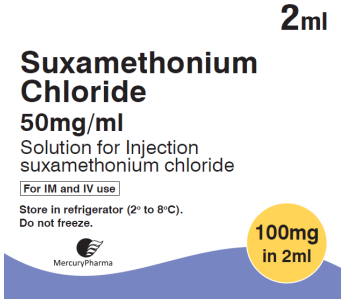
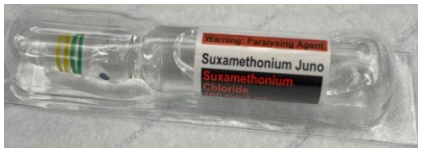
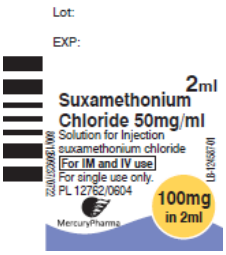
Assessment

The S19A product is identical in active ingredient, strength and storage requirements to the Australian registered product. There are some differences in the excipients (see Table 1 – on next page).

Clinical Recommendations

- Assess the current status of suxamethonium availability in each facility, ensuring all locations of stock are identified.
- Develop a local plan to manage the supply shortage that includes (but is not limited to); assessing local stock holdings, historical stock usage, ability to obtain alternative supply, and ongoing clinical needs.
- Quarantine remaining supplies for procedures where a short duration of paralysis is required, including electroconvulsive therapy.
- Reduce any potential wastage of existing supplies of suxamethonium. The medicine should only be drawn up if intended to be used. Ensure appropriate storage conditions are maintained.
- Pharmacy departments should be aware that due to the upcoming Easter public holidays, wholesaler cut-off times for orders of the S19A product could vary (especially since this is a cold-chain product). Back orders should be placed to ensure timely receipt of supply once it is available.
- Facilities should prepare to switch to rocuronium in the event that suxamethonium stock does not become available prior to the public holidays. Liaison should occur between representatives from the local Pharmacy Departments/Drug and Therapeutics Committees and the relevant clinical experts. High-dose rocuronium is an alternative to suxamethonium for rapid sequence induction and intubation.
- Ensure that sugammadex and/or neostigmine are readily available for reversing block induced by rocuronium. High doses of sugammadex may be required.

Table 1. Comparison between Australian registered and S19A alternative for suxamethonium

Product	*ARTG listed product* **Suxamethonium chloride (Juno) 100 mg/2 mL injection**	*S19A alternative* **Suxamethonium chloride (Mercury Pharma) 100 mg/2 mL injection**
Active ingredient	Suxamethonium chloride dihydrate 100 mg/2 mL	
Excipients	Water for injection Hydrochloric acid for pH adjustment	Sodium acetate BP Water for injection BP
Labelled strength	100 mg/2 mL	50 mg/mL
Storage	Refrigerate 2°C - 8°C Stable for up to 30 days at no more than 25°C	Refrigerate 2°C - 8°C Stable for up to 30 days for a given temperature between 15°C -25°C
Outer packaging artwork		
Ampoule artwork /appearance		

Additionally, in accordance with NSW Health Policy Directive High Risk Medicines Management PD2020_045 clinicians are reminded that:

- Supply of NMBAs such as suxamethonium must be limited to only those critical care areas where there is a clinical use and patients are ventilated and monitored.
- In clinical areas where a small number of doses are kept refrigerated to support cardiopulmonary resuscitation, specially identified secure storage must be used.
- Warning labels should be applied to stored medication including intubation packs to identify them as containing NMBAs.
- A second person check should be undertaken prior to the preparation and administration of NMBAs. While the policy does not mandate a second person check when administered by an authorised prescriber, it is strongly recommended.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where suxamethonium chloride 100 mg/2 mL ampoules are held, prescribed or administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above recommendations to manage the disruption of supply.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Report any incidents associated with this disruption to supply 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.