Issue date
31 January 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 Departments
- Intensive Care Units
- Emergency Departments
- Drug & Therapeutics Committees
- Pharmacy Departments
- NSW Ambulance Service

All other relevant clinicians and clinical departments where these products are prescribed, stored and administered

Expert Reference Group

Content reviewed by:
Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

Review date
July 2024

UPDATED – Potential for error: look-alike fentanyl and suxamethonium Juno® ampoules

What's new in this Safety Information?

One amendment (highlighted in yellow) has been made for clarity (see Page 2).

Situation

There is a potential for errors involving fentanyl Juno® 100 microg/2 mL and suxamethonium Juno® 100 mg/2 mL ampoules due to the similar presentation (or "look-alike" nature) of these products. Near miss incidents involving these products have been reported in South Australia and New South Wales.

Background

Fentanyl is a potent opioid analgesic with a rapid onset and short duration of action. It is indicated for short duration analgesia and sedation during premedication, induction and maintenance of anaesthesia, and in the immediate post-operative period. Fentanyl is a Schedule 8 medication and must be stored in a safe or vault apart from all other medications as per Medication Handling Policy Directive PD2022_032 until immediately prior to use.

Suxamethonium is a depolarising-type neuromuscular blocking agent 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. It is a manufacturer's requirement that suxamethonium ampoules are stored in the refrigerator (between 2-8^{o}C) until immediately prior to use.

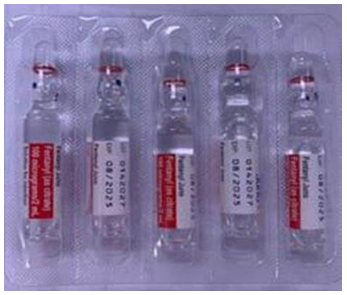
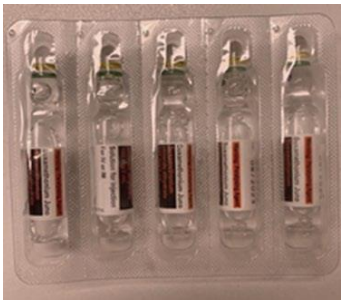
Both fentanyl and suxamethonium are high-risk medicines that have the potential to cause serious harm if used in error. Selection errors involving the inadvertent administration of neuromuscular blocking agents (NMBAs) such as suxamethonium present a potentially catastrophic risk to patient safety resulting from unintended paralysis, respiratory arrest, severe permanent harm, or even death.

Assessment

Both fentanyl Juno® 100 microg/2 mL and suxamethonium Juno® 100 mg/2 mL products are presented in clear glass ampoules of the same shape containing equal volumes (2 mL) of a clear and colourless solution. The packaging and labels of both products have a similar design and colour scheme (see images **below**). Other notable similarities between the products include: no dilution requirement for either medication when used in general anaesthesia, both drugs are likely to be prepared and administered in the same size syringe and both are likely to be prepared at the same time and kept close together prior to administration.

While the drug sponsor is currently working to amend product artworks and designs, it is recommended that clinicians involved in the prescribing, dispensing and administration of these products be made aware of the risk for selection error because of their look-alike presentation, and that local risk mitigation strategies are employed to minimise the risk of selection errors occurring.

PTO

 	 	 
Side by side comparison of suxamethonium Juno® (top) and fentanyl Juno® (bottom)	*Fentanyl Juno® 100 micrograms/2 mL*	*Suxamethonium Juno® 100 milligrams/2 mL*

Clinical Recommendations

In accordance with NSW Health Policy Directive Medication Handling PD2022_032:

- Fentanyl must be stored in the Schedule 8 drug safe separate to the refrigerated storage of suxamethonium. Consideration should be given to storing them in their original packaging until immediately prior to being drawn up.
- Reviews of medication storage areas should be regularly performed to ensure medicines are in their correct locations and any look-alike medicines appropriately flagged and separated.
- Clinicians should adhere to local policy regarding safe and accurate medication administration, including independent second person checking procedures. The independent second check includes (but is not limited to) carefully reading the drug name and concentration to confirm they are correct rather than relying on package/label recognition. While the policy does not mandate a second person check when administered by an authorised prescriber, it is strongly recommended.

In accordance with NSW Health Policy Directive High-Risk Medicines Management PD2020_045:

- Supply of neuromuscular blocking agents such as suxamethonium *"must be limited to only those critical care areas where there is a clinical use and patients are ventilated and monitored."*
- Uncluttered surfaces and separate containers should be used for drawing up, arranging and storing the medicines before administration. The time interval between drawing up and administering a drug should be as short as possible.
- Drugs should be drawn up using one syringe and one ampoule at a time. Syringes should be labelled in accordance with ACSQHC's *National Standard for User-applied Labelling of Injectable Medicines Fluids and Lines*. The label on the ampoule should be checked and matched to that on the syringe.
- When both products are in use, extra precautions should be implemented to separate and differentiate these products including the use of additional stickers or warning labels (requirement for neuromuscular blocking agents as per PD2020_045), separate storage containers and different coloured drawing up syringes (e.g., red plungers for neuromuscular blocking agents – see Australian and New Zealand College of Anaesthetics guidance).
- Ensure that reversal agents for opioids and neuromuscular blocking agents are readily available in clinical areas where these medicines are used. For suxamethonium where there is no specific reversal agent, provide ventilatory support until patient stabilises.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant clinicians and clinical departments where Fentanyl Juno® and Suxamethonium Juno® ampoules may be dispensed or administered.
2. Escalate any concerns to CEC-MedicationSafety@health.nsw.gov.au.
3. Report any incidents associated with Fentanyl Juno® and Suxamethonium Juno® ampoules via the local incident management system (e.g., ims+) and TGA.