Safety Information 004/23

Issue date
20 February 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:
- Palliative Care Units
- 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
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Intranet

Review date
February 2024

Potential for error: look-alike HYDROmorphone and morphine sulfate Medsurge® solution for injection

Situation

There is a potential for error involving HYDROmorphone Medsurge® and morphine sulfate Medsurge® solution for injection products due to the similar presentation (or "look-alike" nature) of the outer packaging and ampoules.

Background

Both HYDROmorphone and morphine are Schedule 8 (S8) opioid analgesics used to treat moderate to severe pain in patients unresponsive to non-opioid analgesia. HYDROmorphone is **5 to 7 times more potent than morphine** and used when other treatment options have failed, are contraindicated, not tolerated or otherwise inappropriate to provide sufficient management of pain.

Both HYDROmorphone and morphine are high-risk medicines that have the potential to cause serious harm if used in error. Selection errors involving the inadvertent administration of potent opioid analgesics such as HYDROmorphone present a potentially catastrophic risk to patient safety resulting from respiratory arrest, hypotension, severe permanent harm, or even death.

Assessment

Both HYDROmorphone Medsurge® and morphine sulfate Medsurge® solution for injection products have similar design and colour scheme in their outer packaging and ampoule labels (see images of examples **below**). All strengths of both medicines currently used in NSW Health are available in amber glass ampoules of the same shape containing equal volumes (1 mL) of a clear colourless to yellowish solution. The HYDROmorphone Medsurge® ampoule colour is different to the originator Dilaudid® ampoules (clear glass ampoules). Other notable similarities between the products include that both drugs are likely to be prepared and administered in the same size syringe and must be stored in a S8 drug safe/cabinet until immediately prior to use.

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.

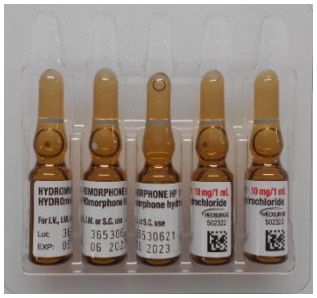
Clinical Recommendations

- Facilities holding stock of the Medsurge brand for both medicines, can consider procuring an alternate brand of either HYDROmorphone or morphine sulfate solution for injection until the issue is resolved.
- Only one medicine should be prepared and labelled 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.

In accordance with NSW Health Policy Directive Medication Handling PD2022_032:

- HYDROmorphone and morphine must both be stored in the Schedule 8 drug safe/cabinet (also adhering to PD2020_045 requirements, see below). Consider storing both in their original packaging until immediately prior to being drawn up.
- Consider the following actions to minimise risks associated with storing and handling of these medicines (not an exhaustive list, see Pages 69-72):
    - where paper-based Schedule 8 drug registers are in use, consider recording morphine sulfate and HYDROmorphone solution for injection in separate drug registers
    - the inclusion of warning labels applied to shelf labels.

PTO

HYDROmorphone Medsurge® 2 mg/1 mL and HYDROmorphone HP Medsurge® 10 mg/1 mL	*Morphine sulfate Medsurge® 10 mg/1 mL and 30 mg/1 mL*
   	   

Clinical Recommendations cont.

- The physical balance of the Schedule 8 medicine must be checked at the time of each transaction.
- 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:

- HYDROmorphone should be stored in a separate Schedule 8 medication storage unit from morphine. In patient care areas where there is only one Schedule 8 medication storage unit, HYDROmorphone must be separated from morphine by storing these medicines on different shelves and by placing HYDROmorphone medicines in a distinctive coloured bag or container (e.g., orange plastic bag).
- HYDROmorphone should not be routinely stored in patient care areas where use is infrequent. High-concentration HYDROmorphone (i.e., 10 mg/1 mL) should not routinely be stored in patient care areas outside of palliative care units. In circumstances when high concentrations are required, the product should be individually dispensed per patient, and removed at the end of the patient care episode.
- Facilities must NOT hold inventory stock of HYDROmorphone injections with strengths greater than 10 mg/1 mL.
- An additional sticker using Tall Man Lettering stating ‘HYDROmorphone’ should be applied to all inpatient HYDROmorphone packets and bottles.
- Naloxone (reversal agent) must be available in all patient care areas where opioid medicines are used.

Required actions for the Local Health Districts/Networks

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