Safety Notice 008/17

DILAUDID® (HYDROmorphone) Oral Liquid 1 mg/mL – Disruption to Supply

6 June 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:

- Palliative Care Services
- Pain Services
- Renal Units
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing
- Drugs and Therapeutics Committees and subcommittees

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission

Clinical Excellence Commission

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Review date

December 2017

Background

DILAUDID® (HYDROmorphone) Oral Liquid 1 mg/mL is currently unavailable due to unforseen manufacturing issues. It is anticipated that normal supply will resume in September 2017.

HYDROmorphone is a potent opioid frequently used to treat moderate to severe, acute, or chronic pain. As other brands of oral liquid HYDROmorphone are not available in Australia, use of an alternative HYDROmorphone formulation (e.g. tablet or injectable) or an alternative opioid agent may be required. HYDROmorphone is 5 to 7 times more potent than morphine, and opioid conversion tools should be used if patients are switched to an alternative opioid.

Because of their high risk nature, errors with HYDROmorphone and other opioids can result in serious patient harm. Converting patients to, or from, HYDROmorphone, or changing the route of administration can be complex and increases the risk of dosing errors; see Safety Alert 001/17 HYDROmorphone: High-risk medicine for more information.

For patients who are able to swallow tablets, DILAUDID® tablets (immediate release HYDROmorphone), 2 mg, 4 mg and 8 mg, are available. Of the three strengths, only the 8 mg tablets are scored.

Two alternative oral liquid opioid formulations are available:

- OXYNORM ® liquid (immediate release oxycodone hydrochloride) 1 mg/mL, 250 mL bottle
- ORDINE® oral solution (immediate release morphine hydrochloride) 1 mg/mL, 2 mg/mL, 5 mg/mL and 10 mg/mL; 200 mL bottle

References

1. PD2015_029 High-Risk Medicines Management Policy http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2015_029
2. Changing to a different opioid in palliative care patients [revised 2016 July]. In: eTG complete [Internet]. Melbourne: Therapeutic Guidelines Limited; 2017 March.

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all stakeholders and clinical departments affected by the shortage of DILAUDID® (HYDROmorphone) Oral Liquid 1 mg/mL
2. Develop a local plan to manage the supply shortage which should include:
    a. an assessment of the current status of DILAUDID® (HYDROmorphone) Oral Liquid available in each facility
    b. reserving existing stocks of DILAUDID® (HYDROmorphone) Oral Liquid 1 mg/mL for situations where it is the only suitable option, e.g. elderly patients, or patients with severe renal impairment, who may not be able to swallow tablets or require small doses
    c. when converting patients to an alternative opioid:
        i. ensuring the availability of locally approved opioid conversion tools and implementing strategies to minimise conversion errors e.g. independent second person check
        ii. ensuring the alternative opioid is commenced at a lower dose than the calculated equianalgesic dose considering patient factors, including age, renal impairment, genetic opioid metabolism, and opioid characteristics (refer to Therapeutic Guidelines[2])
    d. clear communication of any changes to the patient's opioid therapy in the patient clinical file, to nursing staff and to primary healthcare providers.
3. Verbally inform patients/carers affected by the shortage of potential changes to their treatment and provide written dosing information of alternatives.
4. Inform clinicians and clinical departments when supply of DILAUDID® (HYDROmorphone) Oral Liquid 1 mg/mL is reinstated.
5. Ensure a system is in place to document actions taken.