AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Guidance
for nurses

Conserving oral opioid medicines: Strategies and safety considerations

What you need to know?

- There are multiple shortages or disruptions to supply of oral opioid medicines in Australia.
- The Therapeutic Goods Administration (TGA) has approved overseas registered alternative products under Section 19A (S19A), of the Therapeutic Goods Act 1989.
- Conservation strategies that may be considered during the period of shortage include:
    - other treatment options for managing pain relief symptoms, including non-pharmacological and pharmacological options
    - supplying the smallest quantity that is clinically necessary and appropriate for the patient in liaison with the prescriber
    - supporting patients to switch to other opioid or non-opioid medicines as appropriate
    - prioritising preparations of morphine oral liquid for situations where it is not appropriate to disperse or break an alternative opioid in solid dose form or where therapeutic alternatives are contra-indicated or otherwise clinically inappropriate
- When changing or switching between opioid medicines, concentration or formulation, serious errors can occur if dose conversions occur incorrectly, or patients are not educated about such changes.
- There are several opioid conversion resource tools available to assist in determining a suitable dose. Refer to page 7 for a list of resources
- Conservation strategies may not be appropriate for palliative care and end-of-life patients.
- Applying a safe administration checklist helps to mitigate risk when managing changes in availability of oral opioid medicines.

More information on conservation strategies, safety considerations and resources to support safe use of opioids during shortages or supply disruption is included in this guidance. The Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard includes priority actions to reduce opioid medication-related harm, including appropriate prescribing of opioids.

Australia is experiencing shortages or disruption to supply of multiple oral opioid medicine products, with some being discontinued. To assist with supply disruption, the Therapeutic Goods Administration (TGA) has approved overseas registered alternative products under Section 19A (S19A), of the Therapeutic Goods Act 1989.

There are frequent notifications about opioid medicine product availability and the notification period may be short. To minimise the impact on patients, safety considerations and risk mitigations, including conservation strategies, should be considered when responding to changes in the availability of opioid medicines.

Purpose

This guidance has been developed by the Australian Commission on Safety and Quality in Health Care (the Commission) to assist nurses to provide safe and quality health care during disruption to supply of oral opioid medicines in Australia.

Oral opioids are high-risk medicines used to manage severe pain and difficult or laboured breathing in many care settings, including cancer treatment and end-of-life care. To minimise patient harm, safety considerations that nurses should adopt prior to the administration of opioid medicines. Whilst these considerations may not apply in the same way for all patients, particularly those at end-of-life, they are fundamental best practice principles for managing opioids.

Background

Oral opioid medicine products in Australia have been impacted by discontinuations and shortages. The impacted products include:

- Oxycodone capsules
- Morphine oral products
- HYDROmorphone products.

Oral opioids medicine products discontinued during 2024-2025 include:

- morphine sulfate pentahydrate modified-release capsule (MS Mono)
- morphine sulfate pentahydrate immediate-release tablet (Sevredol)

Refer to the TGA for further information on oral opioid medicines supply disruption.

To alleviate supply disruption, the TGA has approved overseas-registered alternative products under S19A, of Therapeutic Goods Act 1989. Refer to Section 19A approvals database for more information. Alternative products may also be available under the Special Access Scheme (SAS), which allows prescribers to apply for use of unregistered products for individual patients.

Conservation Strategies

The following conservation strategies are in response to supply disruptions and discontinuations of oral opioid medicines.

You will need to refer to local policies, procedures and guidelines, and/or liaise with prescribers or your hospital pharmacy or community pharmacy for additional advice and guidance on conservation strategies. If necessary, you may need to also liaise with your local Drug and Therapeutics Committee (DTC) (or equivalent) or Medicines Advisory Committee (MAC). Suggested strategies are listed below.

All oral opioid medicines:

- Provide information to patients on other treatment options for managing pain symptoms, including paracetamol and non-steroidal anti-inflammatories, and nonpharmacological treatments such as splinting, heat packs, ice packs, physiotherapy, exercise and psychological techniques. The Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard includes priority actions to reduce opioid medication-related harm. Other treatment options may not be applicable to palliative care and end-of-life patients.
- Review compliance with opioid stewardship strategies for patients experiencing acute pain and implement where possible. Refer to the Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard for more information.
- Store oral opioid medicines as ward/imprest stock where appropriate to minimise any wastage, in accordance with the relevant state or territory legislative requirements and local policies, procedures and guidelines.
- Ongoing supply disruptions have resulted in the increased need to switching patients to other opioid medicines with potential safety risks. Refer to opioid conversion resource tools and calculators to assist when clinically reviewing suitable opioid dosages, prior to administration. See ‘Changing or switching between opioid medicines’ on page 7 for a list of resources.
- Be alert to any sudden changes in product availability that will impact what oral opioid medicines are available for patients and the contingency plan for when they occur.

Morphine oral liquid:

- Morphine oral liquid preparations should be prioritised for situations where:
  - the intended dose cannot be safely achieved by dispersing or breaking a scored morphine ‘immediate release’ tablet or an alternative opioid in solid dose form
  - the medicine will be administered outside of hospital, and it is inappropriate for an individual (or their family or carer) to break or disperse a tablet formulation of morphine or an alternative opioid in solid dose form
  - therapeutic alternatives are contra-indicated or otherwise clinically inappropriate. For example, excipient allergies
  - there is insufficient evidence for alternative therapeutic agents for the proposed indication or patient group being treated.
- Check for available concentrations (1 milligram/millilitre [mg/mL], 2 mg/mL, 5 mg/mL and 10 mg/mL) prior to administering. Refer to the table in About the shortage of Ordine (morphine) oral liquid or your Pharmacy department to see when the different strengths are expected to return to normal supply
- Alert the prescriber or pharmacist to any other medicines that could potentially contribute to or exacerbate laboured breathing/shortness of breath and ensure other pharmacological and non-pharmacological strategies have been optimised. For example, ensure optimal inhaler technique when administering inhalers to patients.

HYDROmorphone oral liquid:

- Therapeutic Guidelines recommend that use is limited to prescribers experienced in the use of HYDROmorphone.
- Be aware of prescribing restrictions applicable to HYDROmorphone, refer to local policies, procedures and guidelines.
- HYDROmorphone is five times more potent than morphine. Where a patient is switched to HYDROmorphone from an alternative opioid, double check that the dose prescribed represents a safe conversion and contact the prescriber or pharmacist where there are concerns regarding a possible dose conversion error. See ‘Changing or switching between opioid medicines’ on page 7 for a list of resources.

- Renally excreted metabolites of HYDROmorphone can accumulate and lead to dose dependent neurotoxic effects.

Safety considerations

As with all medicines, safe and quality use is supported by best practice principles. Applying a safe administration checklist helps to mitigate risk when managing changes in availability of oral opioid medicines.

Safe administration checklist

BEFORE administering opioid medicines, always check the following are documented on all prescriptions and medication orders (in accordance with state or territory legislative requirements):

- Active ingredient name
- Strength or concentration of product
- Formulation
- Dose:
  - Oral liquids: dose in milligrams (mg) and volume (mL)
  - Tablets/capsules: dose in mg and number of tablets/capsules
  - Maximum daily dose (i.e. in 24 hours)
- Route
- Dosing frequency
- Maximum daily dose (particularly for 'when required' medicines)

To safely administer opioid medicines, always:

- Correctly identify the patient
- Check for any signs of opioid induced ventilatory impairment (OIVI) or sedation according to local policies, procedures and guidelines
- Follow the 'rights' of administration
- Conduct independent double checks according to local policies, procedures and guidelines

Table 1: Potential safety issues to be considered prior to administering oral opioid medicines.

Consideration	Details
Avoid misinterpretation	Always check the dose in milligrams (mg) rather than volume (mL) for oral liquids is prescribed as the available concentration(s) of products may change. For example, if morphine oral liquid (5 mg/ mL) is prescribed ensure the dose in mg and equivalent dose in mL is documented. Always check the dose and number of tablets/capsules is prescribed as the availability of different strengths may change.

Consideration	Details
Appropriate dosing	When initiating, changing or switching between opioids, concentration or formulation, take care when reviewing the starting dose and dosage intervals. There are multiple opioid conversion resource tools and calculators available to assist when reviewing a suitable dose prior to administration, see page 7 for a list of resources. Advice should be sought from your pharmacist or medicines information service if there is limited experience with opioid conversions. Be aware of opioid ceiling doses. General Practitioners must be able to justify a decision to titrate dosage to 100 mg or more oral morphine equivalent (OME) per day and should avoid increasing dosage to 100 mg or more OME per day without specialist involvement. Liaise with the prescriber or pharmacist if you have any concerns. See RACGP – Overview of opioid analgesics for more information.
Risk mitigation	Ensure systems and protocols are in place for clinicians to monitor and manage opioid analgesic adverse effects such as nausea, constipation, sedation, and signs of overdose including respiratory depression (OIVI). For more information refer to the Recognising and Responding to Acute Deterioration Standard. Awareness of product availability (including SAS and S19A products) of opioid medicines, including strength, concentration and formulation can assist with minimising safety risks to patients at the point of administration. View the full patient record in Real Time Prescription Monitoring (RTPM) before administering an oral opioid medicine, to assist with clinical decision making. Consider enrolling patients onto the Take Home Naloxone Program, when switching or changing opioid oral medicines. For hospital settings: Be aware of what opioid medicines are available for initiation and continuation on the local/state-wide formulary. If a prescribed product is not within the formulary guidance, contact your hospital pharmacy or local Drug and Therapeutics Committee.
Monitoring	Careful observation of an opioid-naïve* patient is required when commencing an opioid medicine, and when changing a patient to an alternative medicine, formulation or route of administration. Monitoring should continue until the patient is stabilised or as appropriate. For more information refer to the Recognising and Responding to Acute Deterioration Standard.
Formulation (or dosage form)	Consider the suitability of the medicine's formulation for the intended clinical use. For example, modified release preparations are typically more appropriate for long-term use. Modified release

Consideration	Details
	preparations should be swallowed whole and not halved or crushed. Check whether a solid oral dosage form can be crushed and/or the most appropriate formulation should be sought for individuals with swallowing difficulties. For instance, check Don't rush to crush or seek pharmacist advice.
Product factors	**Storage:** Be aware of 'look-alike, sound-alike' (LASA) issues. Several examples of LASA medicine names are present in the opioid therapeutic group (e.g. HYDROmorphone and morphine). Check the different storage requirements and expiration dates (e.g. both the manufacturer's expiry date and once a morphine oral liquid bottle is opened) of alternative products, and ensure appropriate storage occurs and that information is communicated to patients who are usually responsible for the storage of their own medicines at home. **Labelling:** SAS/S19A products have the potential for the label to contain information in a language other than English. If you are unsure of the details of a product, speak to your hospital pharmacy, community pharmacy, local Drug and Therapeutics Committee or MAC for translated information.
Patient factors	The suitability and safety of alternative medicines should be considered with patient factors including: • Sensitivities and previous adverse drug reactions (ADRs) • Organ impairment, such as liver or kidney, may need specialist input to determine the choice of opioid product and appropriate dosing • Manual dexterity in opening bottles versus 'blister packs' • Visual impairment could lead to incorrect dose administration, particularly when similar packaging and colours are used for opioid medicines • Cost impact on adherence when alternative medicines are initiated. SAS and some S19A alternatives are not PBS subsidised. Speak to the pharmacist or prescriber regarding any factors relevant to your patient, that may be of concern.
Patient counselling	Changes to medicines present an opportunity to promote discussion and shared decision-making with patients and their family or carers. Some key factors to discuss when counselling an alternative medicine include: • Reconfirming the clinical indication

Consideration	Details
	• Clear instructions and confirmation of what it replaces (for example, brand or medicine name and differences in packaging) • Discussing any potential drug interactions • Dosing instructions and the need for any specialised measuring device • Supply of written information in English (obtain translated version from supplier(s) if required) • Management of any new side effects.
Transition of care	Ensure that opioid medicines are available and can be accessed when patients transition to different settings. For example, from hospital to community/nursing homes or metropolitan to rural/remote areas. Ensure any changes are communicated to all healthcare practitioners, and people involved in the care of the patient (e.g. their family and/or carer). Encourage the use of an up-to-date medicines list. Avoid the use of brand names. Use the active ingredient name(s) when communicating medicines-related information during transitions of care. Refer to Principles for safe and high-quality transitions of care for more information.
Electronic medication management (eMM) systems	eMM systems need to be reviewed and updated to reflect any product changes to prevent selection errors at the point of prescribing and administration. The review should be overseen by the local medicines governance committee, for instance, the Drug and Therapeutics Committee (or similar).

*opioid-naïve = Patients who have not received opioid analgesics in the 30 days before the acute event or surgery.

Changing or switching between opioid medicines

This includes changing, or switching, from one opioid to another or from one formulation or strength to another.

When changing or switching between opioid medicines, concentration or formulation, serious errors can occur if dose conversions are not correct, or patients are not educated about the changes.

There are multiple opioid conversion resource tools available to assist in determining a suitable dose and reviewing a dose prior to administration. Check which tool is preferred by your local Palliative Care, Acute Pain Management Service, or prescriber. Advice should be sought, from your pharmacist or medicines information service if there is limited experience with opioid conversions.

Resources include:

- Australian and New Zealand College of Anaesthetists (ANZCA) Faculty of Pain - Opioid Calculator
- eviQ Opioid Conversion Calculator
- Safer Care Victoria: Opioid conversion ratios – Guidance document
- palliMEDS app (For download onto smartphones)
- eTG complete
- Australian Medicines Handbook

These resources do not take into consideration the available concentrations of opioid medicine at the point of prescribing.

Additional care should be taken when calculating and reviewing dosages, particularly when both milligrams (mg) and volume (mL) is prescribed for oral opioid liquids. Liaise with the prescriber and communicate available concentrations and current information.

Useful resources

- About the shortage and discontinuation of oral opioid products [online]. Therapeutic Goods Administration (TGA). 28 August 2024 [cited 10 September 2024]
- About the shortage of Ordine (morphine) oral liquid [online]. Therapeutic Goods Administration (TGA). 28 August 2024 [cited 10 September 2024]
- Therapeutic Goods Administration (TGA) publishes medicine updates and information on approved products under Section 19A, on the TGA Section 19A approvals database.
- Therapeutic Guidelines [online]. Melbourne: Therapeutic Guidelines Limited.
- Australian Medicines Handbook [online]. Adelaide: Australian Medicines Handbook Pty Ltd.
- Don't Rush to Crush [online]. Advanced Pharmacy Australia [also available through eMIMS, MIMS Online and AusDI via states and territory medicines information portals]
- Australian Commission on Safety and Quality in Health Care guidance on conserving medicines within a focus on medicines shortages.
- Australian Commission on Safety and Quality in Health Care Principles for safe selection and storage of medicines provides guidance on risk reduction strategies to address safe selection and storage of all medicines.
- Australian Commission on Safety and Quality in Health Care Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard
- Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service (NSQHS) Medication Safety Standard
- Australian Department of Health and Aged Care Medication management in residential aged care facilities guiding principles
- Australian Department of Health and Aged Care Medication management in the community guiding principles
- Australian Commission on Safety and Quality in Health Care Real-time prescription monitoring
- Australian Commission on Safety and Quality in Health Care Real-time prescription monitoring - Fact sheet for prescribers and pharmacists
- Australian Commission on Safety and Quality in Health Care Real-time prescription monitoring: Clinical risk management
- Australian Commission on Safety and Quality in Health Care Principles for safe and high-quality transitions of care
- The Royal Australian College of General Practitioners (RACGP) Prescribing drugs of dependence in general practice, Part C2 – The role of opioids in pain management – Chapter 6 Overview of opioid analgesics
- The Pharmaceutical Benefits Scheme PBS website
- Medicines and Palliative Care Information Resources. palliAGED. [cited 10 September 2024]

State and Territory safety alerts and guidance

- NSW Health: Safety Alert 007/24 - UPDATED: Changes to supply of morphine oral liquid in Australia (21 May 2024).
- SA Health: Safety Alert 01/24 – Discontinuation of several oral opioid products (February 2024)
- SA Health: Safety Alert 04/24 – Discontinuation of Several Oral Opioid Products – Update (May 2024)

- SA Health: Safety Alert 06/24 – Limited Availability of Several Oral Opioid Liquid Products (June 2024)
- QLD Health: Patient Safety Notice 11/2024 – Constrained supply of morphine oral liquid (17 July 2024)
- QLD Health: Fact sheet – Constrained supply of morphine oral liquid (17 July 2024)

Find out more

For more information, visit TGA Medicine Shortage Reports Database or contact the Commission at medsafety@safetyandquality.gov.au or call 1800 304 056.

safetyandquality.gov.au