Morphine oral liquid availability

Keywords

morphine, drug shortage, drug registration, Therapeutic Goods Administration

Aust Prescr 2024;47:30 https://doi.org/10.18773/ austprescr.2024.007 Morphine is an essential medicine that is used for a range of indications, including short-term management of severe pain, difficult or laboured breathing during end-of-life care, and neonatal abstinence syndrome secondary to opioids.

In November 2023, all strengths of Ordine, the only registered brand of morphine oral liquid in Australia, were discontinued. All supplies of Ordine are expected to be depleted by May 2024.¹

To help manage the discontinuation of Ordine oral liquid, the Therapeutic Goods Administration (TGA) has granted approval for the supply of several overseas-registered morphine oral liquid products under section 19A of the *Therapeutic Goods Act 1989* (Table 1).¹ There may be additional approved alternatives from other sponsors available in the future. Section 19A medicines are not registered in Australia, but are allowed to be imported and supplied in place of a registered medicine that is unavailable or in short supply.¹ Some of the overseasregistered products have been approved for subsidised supply through the Pharmaceutical Benefits Scheme.²

Information for pharmacies regarding how to order the alternative morphine oral liquid products can be found

on the Ordine discontinuation page on the <u>TGA website.</u>¹ Prescribers should check with the patient's pharmacy regarding product availability before prescribing.

Morphine is a high-risk medicine that may cause significant patient harm if used in error. As there are multiple alternative morphine oral liquids, with different strengths, pack sizes (volumes) and packaging, health professionals need to exercise caution when prescribing, dispensing or administering these alternative products. To reduce the risk of errors, doses should be communicated in milligrams as well as millilitres. Patient and carer education will be important if an existing patient is switched to a different product.

Health professionals also need to be aware that some overseas-registered morphine oral liquid products contain different excipients (e.g. ethanol and sucrose) compared to the Ordine products. The amount of ethanol is an important consideration if the patient is pregnant or breastfeeding, has a history of alcohol use, has chronic liver disease or epilepsy, or is a child.^{3,4} Some alternative products also contain parahydroxybenzoates as excipients, which may cause allergic reactions.³

Table 1 Alternative morphine oral liquid products approved under section 19A of the Therapeutic Goods Act 1989¹⁻³ [NB1] [NB2]

Product	Size	Sponsor	Contains ethanol	Contains sucrose	Contains parahydroxybenzoates	PBS listed
morphine sulfate 2 mg/mL oral solution (Hikma)	100 mL, 500 mL bottles	Medsurge Healthcare Pty Ltd	no	no	no	yes
morphine sulfate 2 mg/mL oral solution (Martindale Pharma)	100 mL, 300 mL, 500 mL bottles	Link Medical Products Pty Ltd	yes	yes	yes	yes
morphine hydrochloride 10 mg/mL oral drops (Morphine HCl Streuli)	20 mL bottles	Medsurge Healthcare Pty Ltd	yes	no	yes	no

PBS = Pharmaceutical Benefits Scheme

NB1: Information is current at 08 January 2023. Additional products may become available. Check the Therapeutic Goods Administration and Pharmaceutical Benefits Scheme websites for updates.

NB2: These products are approved from 1 December 2023 to 31 July 2025.

REFERENCES

- Therapeutic Goods Administration. About the discontinuation of Ordine (morphine) oral liquid. Department of Health and Aged Care; 2023. www.tga.gov.au/safety/shortages/information-about-major-medicineshortages/about-discontinuation-ordine-morphine-oral-liquid [cited 2024 Jan 8]
- Pharmaceutical Benefit Scheme. PBS arrangements due to discontinuation of the Ordine brands of morphine hydrochloride trihydrate oral liquids effective 1 December 2023. Department of Health and Aged Care; 2023. www.pbs.gov.au/info/news/2023/12/pbs-arrangements-due-todiscontinuation-of-the-ordine-brands [cited 2024 Jan 8]
- NSW Health. Safety Notice 028/23: Discontinuation of all strengths of immediate-release morphine hydrochloride trihydrate (Ordine[®]) oral solution in Australia. 2023. www.health.nsw.gov.au/sabs/pages/default.aspx [cited 2024 Jan 8]
- Australasian Neonatal Medicines Formulary group. Morphine Oral. Version 4. 2023. www.anmfonline.org/clinical-resources/ [cited 2024 Jan 8]