

19 May 2021: Information from Australian Government Department of Health Medicine Shortages Management Section

You may have heard concerns about supply disruptions to opioid medicines that are of particular importance in palliative care settings. I am writing to let you know what we are doing to manage these shortages and provide you with information in case you receive enquiries from your members.

We have been notified of supply disruptions for two medicines: Dilaudid (hydromorphone) oral liquid and MS Contin (morphine) granules for suspension. We are actively working on mitigation strategies for these shortages to minimise impact on patients.

Yesterday we convened a Medicine Shortages Action Group (MSAG) to discuss potential clinical strategies to assist patients. MSAGs are collaborative, short-term working groups that allow us to hear directly from relevant stakeholders (including health professionals and affected patient organisations) and discuss potential clinical management options of a shortage. Work with the MSAG is ongoing and we will provide you with an update as soon as we can.

We have also approved the temporary supply of an overseas alternative medicine under section 19A of the *Therapeutic Goods Act 1989* to assist with the hydromorphone oral liquid shortage. This morning we published [a web statement](#) that is intended to let health professionals know about the upcoming availability of the overseas medicine and, importantly, the **presence of sulfites** in the medicine. The alternative medicine is not yet available in the marketplace but, once it becomes a possible option for patients, the presence of sulfites may be an important consideration for some of your members.

To minimise distress, **at this stage we are not actively targeting our communications about this shortage to patients and consumers**. We are working hard to mitigate the shortage in a number of ways and intend to reach a broader audience, including patients, with more complete information soon.

Although we are not specifically intending to reach consumers and patients at this time, we understand that many of your members may see this web statement and come to you as a trusted source of information. We have drafted some key messages below to assist you to answer any questions. Please feel free to contact us if you have any further questions.

We will be in touch soon to provide you with updates on this and any other prominent shortages.

Information to support web statement

Background

- The Therapeutic Goods Administration (TGA) has been notified of supply disruptions to several opioid medicines commonly used in the palliative care setting. The TGA is actively working to minimise the impact on Australian patients.
- The affected medicines are Dilaudid (hydromorphone) oral liquid and MS Contin (morphine) granules for suspension.

Mitigation with temporary supply of overseas alternative (19A) medicine

- The TGA has authorised the supply of an alternative overseas (19A) product, HYDRORomphone Hydrochloride 1mg/mL oral solution, USP 473 mL (Rhodes) (**Rhodes HYDRORomphone**), to address the current shortage of DILAUDID oral liquid.
- **ALLERGY WARNING:** Rhodes HYDRORomphone is **contraindicated** in patients with hypersensitivity to sulfites due to the presence of sodium metabisulfite. Sulfites are not declared on the medicine label.
- Information about the approval of Rhodes HYDRORomphone has been published in the TGA's online [Section 19A database](#).

Accessing the overseas alternative (19A) medicine

- 'Section 19A' alternative products can be dispensed the same way as the Australian registered products, by a pharmacist filling the usual prescription. Patients can ask their pharmacist to contact the section 19A approval holder to enquire about supply if their usual medicine is unavailable.
- The section 19A approval holder for Rhodes HYDRORomphone is Medsurge Healthcare. The company has distributed a Dear Health Care Professional Letter providing further information on this product. **Health professionals can contact them on 1300 788 261 to arrange supply of Rhodes HYDRORomphone.**
- In the event that a section 19A product is unsuitable or unavailable, the Special Access Scheme (SAS) is an alternative pathway for health practitioners to access unapproved medicines for as single patient. This is assessed on a case by case basis. More information can be found on the TGA website at: www.tga.gov.au (click on 'Special Access Scheme' under 'Health Professionals' on the homepage).

PBS listing

- The section 19A alternative product is not currently listed on the PBS. You can contact the approval holder, Medsurge Healthcare, for further information about PBS listing.