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13th September 2023

RE: Unavailability of an Australian registered hydromorphone hydrochloride 1mg/mL oral liquid product and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act, 1989.*

Dear Healthcare Professional,

Due to the unavailability of an Australian registered **hydromorphone hydrochloride 1mg/mL oral liquid**, LINK has arranged the supply of HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP 473mL (Hikma), registered and marketed in the United States. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30th September 2024**.

HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP 473mL (Hikma) is approved for use under Section 19A for the following indication:

> *Short-term management of severe pain for which other treatment options have failed, are contraindicated, not tolerated or otherwise inappropriate to provide sufficient management of pain.*

Please refer to appropriate clinical references when prescribing HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP 473mL (Hikma).

The table below outlines details of the section 19A approved product. If you require further information, please refer to the US Product Information attached to this letter.

Product Characteristics	19a Product HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP (Hikma)
Presentation	clear, red solution Bottle of 473mL
Storage	Store at 20° to 25°C Dispense in a tight, light-resistant, child-resistant container
Excipients	methylparaben propylene glycol propylparaben purified water raspberry blend saccharin sodium sorbitol solution FD&C Red No. 40 Hydromorphone Hydrochloride Oral Solution 1mg/mL USP (Hikma) may contain traces of sodium metabisulfite.

Please note: CONTAINS SULFITES, SORBITOL & SACCHARIN
These excipients are not declared on the product label

As outlined in the US prescribing information, **HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP 473mL (Hikma)** contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Use of **HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP 473mL (Hikma)** is contraindicated in patients with hypersensitivity to sulfite-containing medications.

Prior to dispensing, pharmacists should determine if this product is suitable for the patient.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION 1mg/mL USP (Hikma)** should be reported by healthcare professionals and patients to Link Pharmacovigilance.
This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Link Pharmacovigilance can be contacted by phone on **1800 181 060** or via email at pv@linkhealthcare.co

For further information please contact Link Healthcare Customer Service on **1800 181 060** or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to relevant staff members in your organisation.

Yours sincerely,

Kay Roweth

Kay Roweth
Unlicensed Medicine Associate