

10 October 2023

**Shortage of DBL LEUCOVORIN CALCIUM folinic acid 300 mg/30 mL (as calcium folinate) injection vial and alternative supply arrangement under Section 19A of the Therapeutic Goods Act**

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **DBL LEUCOVORIN CALCIUM folinic acid 300 mg/30 mL (as calcium folinate) injection vial (AUST R 116688)** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

**Calcium Folate 300 mg/30ml Solution for injection or infusion vial (Hikma/Consilient UK)**, are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until **30 April 2024**.

**Calcium Folate 300 mg/30ml Solution for injection or infusion vial (Hikma/Consilient UK)** are approved for use under Section 19A for the following indication:

*Reducing the toxicity and circumventing the effect of folic acid antagonists, if therapeutically desired.*

**Calcium Folate 300 mg/30ml Solution for injection or infusion vial (Hikma/Consilient UK)** are registered in the United Kingdom and are packaged in English language. The UK section 19a approved product is identical in active ingredient, strength and dose form to the Australian registered **DBL LEUCOVORIN CALCIUM folinic acid 300 mg/30 mL (as calcium folinate) injection vial (AUST R 116688)**. The two differ in excipient ingredients as outlined in the table below.

	<b>ARTG Product</b> DBL LEUCOVORIN CALCIUM folinic acid 300 mg/30 mL (as calcium folinate) injection vial (AUST R 116688)	<b>S19a Approved product</b> Calcium Folate 300 mg/30ml Solution for injection or infusion vial (Hikma/Consilient UK)
<b>Excipient Ingredients</b>	<ul style="list-style-type: none"> <li>• Sodium chloride</li> <li>• Water for injections</li> <li>• Sodium hydroxide and/or hydrochloric acid (used to adjust pH)</li> </ul>	<ul style="list-style-type: none"> <li>• Trometamol</li> <li>• Hydrochloric acid (for pH adjustment)</li> <li>• Sodium hydroxide (for pH adjustment)</li> <li>• Water for injections</li> </ul>

For dosing and administration information, please refer to the Australian Product Information for **DBL LEUCOVORIN CALCIUM folinic acid 300 mg/30 mL (as calcium folinate) injection vial (AUST R 116688)** available at <https://www.ebs.tga.gov.au/>

**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 **Calcium Folate 300 mg/30ml Solution for injection or infusion vial (Hikma/Consilient UK)**, should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at [sas@orspecpharma.com](mailto:sas@orspecpharma.com). Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email [sas@orspecpharma.com](mailto:sas@orspecpharma.com).

Yours sincerely,



Deon Scheepers  
Managing Director  
ORSPEC Pharma