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A CLINIGEN COMPANY

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RE: Shortage of LEUCOVORIN CALCIUM folinic acid (as calcium folinate) 50mg/5mL injection USP ampoule and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **LEUCOVORIN CALCIUM folinic acid (as calcium folinate) 50mg/5mL injection USP ampoule (Aust R 61885)**, LINK has arranged the supply of an alternative product, ***Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection*** **(vial)** registered and marketed in *Germany.*

Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection (vial) is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **29 August 2022.**

Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection (vial) are indicated for:

> *Following high dose methotrexate therapy to reduce toxicity (leucovorin rescue). It is also indicated after inadvertent overdosage with methotrexate and in impaired methotrexate elimination.*

The s19A approved *German* product is identical in active ingredient and strength to the Australian registered product. It contains the following additional excipient ingredients: water for injections, sodium chloride, sodium hydroxide for pH adjustment, hydrochloric acid for pH adjustment, nitrogen as a protective gas.

Please refer to the Australian Product Information for **LEUCOVORIN CALCIUM folinic acid (as calcium folinate) 50mg/5mL injection USP ampoule (Aust R 61885)** (available at https://www.ebs.tga.gov.au) when prescribing and administering ***Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection (vial).***

Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection (vial) are registered in ***Germany*** with the outer package and package insert in both English and German. The active ingredient, strength and dosage form included on the vial label are in English and German.

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 ***Eurofolic folinic acid (as calcium folinate hydrate) 50mg/5mL solution for injection (vial)*** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **LEUCOVORIN CALCIUM folinic acid (as calcium folinate) 50mg/5mL injection USP ampoule (Aust R 61885).**

Yours sincerely,

C Griffin

Charlotte Griffin
Medicine Access Associate