



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

[www.propg.com.au](http://www.propg.com.au)

Dear Healthcare Professional,

**Shortage of DBL Aciclovir 250mg/10mL Intravenous infusion injection vial (AUST R: 56809) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.**

The Australian registered medicine, DBL Aciclovir 250mg/10mL Intravenous infusion injection vial (AUST R: 56809) sponsored by Pfizer Australia Pty Ltd, is in short supply due to manufacturing issues.

Pro Pharmaceuticals Group has been able to arrange supply of **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)** as an alternative product on a temporary basis. 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 **30<sup>th</sup> November 2024** for the following indication(s):

*Aciclovir intravenous infusion is indicated for the purpose of:*

1. *Promoting resolution of acute clinical manifestations of mucocutaneous Herpes simplex virus infections in immunocompromised patients.*
2. *Treatment of severe first episode primary or non-primary genital herpes in immune competent patients.*
3. *Treatment of acute manifestations of Varicella zoster virus infection in immunocompromised patients.*
4. *Treatment of shingles (Varicella zoster virus infection) in immune competent patients who show very severe acute local or systemic manifestations of the disease. Benefits can be expected in patients with rash duration shorter than 72 hours. The use of the intravenous infusion may be warranted in only a small subgroup of immune competent patients with shingles.*
5. *Treatment of Herpes simplex encephalitis.*

The section 19A product **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)** is registered and marketed in United Kingdom by Wockhardt UK Ltd and therefore all labelling is in English.

A comparison table between the Australian registered product and the section 19A product is given below:

	<b>ARTG product:</b>	<b>S19A product:</b>
	Aciclovir 250mg/10mL Intravenous infusion injection vial (AUST R: 56809)	Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)
<b>Presentation</b>	Sterile solution for infusion	Powder for solution for infusion *Requires reconstitution
<b>Excipients</b>	Sodium hydroxide Water for injections	Sodium hydroxide
<b>Storage</b>	Store below 25°C Do not refrigerate	Unopened: - Do not store above 25°C - Keep the vials in the outer carton  After reconstitution: - Do not store above 25°C - The reconstituted or diluted solutions should not be refrigerated

Please note that unlike the Australian registered product, the section 19A product **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)** requires reconstitution prior to administration and should be used immediately. Please refer to the product information leaflet for reconstitution and storage requirements enclosed with **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)**.

For recommended dosing information for the approved indications, please refer to the Australian Product Information for DBL Aciclovir 250mg/10mL Intravenous infusion injection vial (AUST R: 56809) available at: [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au).

### **Adverse Event Reporting**

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)** should be reported by patients and healthcare professionals to Pro Pharmaceuticals Group on 1300 077 674 or email [regulatory@propg.com.au](mailto:regulatory@propg.com.au). Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **Aciclovir 250mg powder for solution for infusion (Wockhardt, UK)** should be reported to Pro Pharmaceuticals Group on 1300 077 674 or email [regulatory@propg.com.au](mailto:regulatory@propg.com.au)

For any orders, please contact Pro Pharmaceuticals Group on 1300 077 674 or email [orders@propg.com.au](mailto:orders@propg.com.au)

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

For further information, please contact Pro Pharmaceuticals Group on 1300 077 674 or email [info@propg.com.au](mailto:info@propg.com.au)

Sincerely,

Sandip Manku  
Director  
Pro Pharmaceuticals Group