



Safety Notice 012/16

Aciclovir intravenous infusion preparations – Disruption to supply (Revised on 13 December 2016)

13 December 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Emergency Departments
- Intensive Care Units
- Infectious Diseases Physicians
- Directors of Medical Services
- Directors of Nursing
- Directors of Pharmacy
- Neurology Departments

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission
- HealthShare
- AMS Expert Advisory Committee

Clinical Excellence Commission

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Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

May 2017

Background

An out of stock notification has been received for aciclovir intravenous infusion preparations from the drug sponsor, Pfizer. This stock situation is due to unexpected maintenance work on the manufacturing line causing delay in production. There are current supply constraints with an expected out of stock period until **mid to late December 2016**.

Medsurge Healthcare P/L is able to supply an alternative product *Aciclovir 25 mg/mL Concentrate for solution for infusion* in both 250mg/10mL and 500mg/20mL vials on a temporary basis; this product is registered and marketed in the United Kingdom by Claris Lifesciences UK Limited. Although this product is not registered in Australia it can be supplied under an exemption granted by the Therapeutic Goods Administration under section 19A of the Therapeutic Goods Act 1989.

Oral formulations of aciclovir are available.

Aciclovir intravenous infusion preparations are indicated for a number of manifestations of severe herpes simplex and varicella zoster infections.

The affected products are:

Presentation	AUST R
DBL™ Aciclovir Intravenous Infusion 250 mg/10 mL vials, 5 pack	56809
DBL™ Aciclovir Intravenous Infusion 500 mg/20 mL vials, 5 pack	56810
Aciclovir Intravenous Infusion 250 mg in 10 mL ampoules, 5 pack (Pfizer)	66116
Aciclovir Intravenous Infusion 500 mg in 20 mL ampoules, 5 pack (Pfizer)	66117

Further Information

Pfizer has a limited quantity on hand of aciclovir intravenous infusion for restricted supply on the basis of immediate patient use.

Therapeutic Goods Administration <http://apps.tga.gov.au/prod/MSI/Search/Details/aciclovir>

Suggested actions by Local Health Districts/Networks (until supply is reinstated):

1. Distribute this notice to all stakeholders and all clinical departments.
2. Assess the current status of aciclovir intravenous infusion preparations availability in each facility, ensuring all locations of stock are identified.
3. Remove and quarantine stock from clinical areas where aciclovir intravenous infusion preparations are not routinely used.
4. Consider restricting intravenous aciclovir to Infectious Disease approval only, using existing antimicrobial stewardship processes.
5. Limit treatment with aciclovir intravenous infusion preparations to those patients where treatment with an **intravenous** preparation is critical, such as patients with likely herpes simplex encephalitis, ophthalmic herpes zoster or immunocompromised patients with disseminated herpes zoster.
6. Ensure a system is in place to document actions taken.