24 May 2022

Shortage of EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vials 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 the Australian registered **EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vials (AUST R: 287040)** ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

Cidofovir Injection USP 375mg/5ml vials, are NOT registered in Australia and supply is granted under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until 31 July 2022.

Cidofovir Injection USP 375mg/5ml vials, are approved for use under Section 19A for the following indications:

> *Cidofovir is indicated in adults for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS).*

The s19A approved USA product is identical in active ingredient and strength to the Australian registered product. The two products differ in their storage conditions.
These differences are noted below:

	ARTG product (EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vial - AUST R 287040**)**	**S19A product (**Cidofovir Injection USP 375mg/5ml vials**)**
Storage	Store at a temperature below 25°C. Do not refrigerate or freeze.	Cidofovir Injection, USP should be stored at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)

Cidofovir Injection USP 375mg/5ml vials, are registered in the United States and are packaged in English language. Please disregard the foreign product insert and refer to the Australian Product

Information for **EMPOVIR cidofovir 375 mg/5 mL concentrated injection for infusion vials (AUST R: 287040)** available at https://www.ebs.tga.gov.au/ for prescribing information.

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 **Cidofovir Injection USP 375mg/5ml vials,** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at 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.

Yours sincerely,

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