Fresenius Kabi Canada Ltd.
165 Galaxy Blvd., Suite 100
Toronto, ON, M9W 0C8
Canada

Importation of US-authorized Acyclovir Injection, USP
due to the Current Shortage of Canadian-authorized Acyclovir Sodium Injection, 50 mg/mL

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2025/09/02

Dear Healthcare professionals including Infectious Disease Physicians, Hospital Pharmacists, Family Physicians, Public Health Officials, Nurses and Nurse Practitioners, and Healthcare Professionals at identified points of use:

There is a critical shortage of Acyclovir Sodium Injection in Canada. Given the medical necessity of Acyclovir Sodium Injection and to help mitigate the current shortage, Health Canada has permitted the exceptional, temporary importation, distribution, and sale of Fresenius Kabi's US-authorized Acyclovir Injection, USP, with English-only labels.

Health Canada has accepted the addition of Fresenius Kabi Canada's product to the List of Drugs for Exceptional Importation and Sale (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html).

In Canada, Acyclovir Sodium Injection, 50 mg/mL is indicated for:

- The treatment of initial and recurrent mucosal and cutaneous herpes simplex (HSV-1 and HSV-2) infections and varicella-zoster (shingles) infections in immunocompromised adults and children.
- Severe initial episodes of herpes simplex infections in patients who may not be immunocompromised.

The US-authorized drug product has the **same active ingredient (acyclovir sodium), strength (50 mg/mL), dosage form (solution), and route of administration (intravenous)** as the Canadian-authorized Acyclovir Sodium Injection drug product (DIN 02236926). The products, however, **differ in the indications, packaging, and reconstitution and administration instructions (see summary table below)**.

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	US-authorized Drug Product	Canadian-authorized Drug Product
Product Name	Acyclovir Injection, USP	Acyclovir Sodium Injection
Identifying Code	10 mL vial: NDC 65219-622-02 (Single Vial) NDC 65219-622-10 (Unit of10) 20 mL vial: NDC 65219-624-04 (Single Vial) NDC 65219-624-20 (Unit of 10)	DIN 02236926
Indications	- treatment of initial and recurrent mucosal and cutaneous herpes simplex (HSV-1 and HSV-2) in immunocompromised patients - treatment of severe initial clinical episodes of herpes genitalis in immunocompetent patients - treatment of varicella-zoster (shingles) infections in immunocompromised patients. Includes two additional indications not approved in Canada: - treatment of neonates with herpes simplex infections - treatment of herpes simplex encephalitis. The safety and efficacy of Acyclovir Injection has been evaluated in pediatric patients, including neonates.	- treatment of initial and recurrent mucosal and cutaneous herpes simplex (HSV-1 and HSV-2) infections and varicella-zoster (shingles) infections in immunocompromised adults and children - treatment of severe initial episodes of herpes simplex infections in patients who may not be immunocompromised. Health Canada has authorized an indication for pediatric use in patients aged 1 year to < 18 years.
Packaging	**Single dose glass vials**	**Single dose plastic vials**
Reconstitution & Administration	The calculated dose should be removed and added to any appropriate intravenous solution at a volume selected for administration during each 1-hour infusion. Infusion concentrations of **approximately 7 mg/mL or lower are recommended**. A maximum dose	The calculated dose of the solution should be removed and added to an appropriate intravenous solution listed below at a volume selected for administration during each 1-hour infusion. **Infusion concentrations exceeding 10 mg/mL are not**

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	US-authorized Drug Product	Canadian-authorized Drug Product
	equivalent to **20 mg/kg every 8 hours** should not be exceeded for any patient. Standard, commercially available electrolyte, and glucose solutions are suitable for intravenous administration; biologic or colloidal fluids (e.g., blood products, protein solutions, etc.) **are not recommended.** Rapid or Bolus intravenous injection must be avoided. Once diluted for administration, each dose should be used within 24 hours.	**recommended**. A maximum dose equivalent to **500 mg/m2 every 8 hours** should not be exceeded for any patient**.** **Solutions for Intravenous Infusion:** 5% Dextrose Injection, 5% Dextrose and 0.9% Sodium Chloride Injection, Normal Saline Injection and Lactated Ringer's Injection. **Incompatibility:** Acyclovir Sodium Injection should not be added to biologic or colloidal fluids (e.g., blood products, protein hydrolysates or amino acids, fat emulsions). Once diluted, the admixtures are to be administered within 24 hours of the initial preparation. The admixtures are not to be refrigerated.

Healthcare professionals are advised to refer to the Canadian Product Monograph for Acyclovir Sodium Injection, 50 mg/mL (DIN 02236926) available in English and French on the Health Canada Drug Product Database (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html) for proper use of the imported product, including information for the:

- indications
- contraindications
- warnings and precautions
- adverse reactions
- reconstitution instructions
- dosage and administration
- storage conditions
- handling instructions

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Information on the imported product

Brand Name	Dosage form, strength, and route of administration	Product description and packaging	Country of authorization and identifying code	Foreign authorization holder	Importer in Canada
Acyclovir Injection, USP	Solution, 50 mg/mL, Intravenous	Clear, tubular, glass vial. Sterile, aqueous solution for intravenous infusion. Available in cartons of 10 vials.	United States of America 10 mL vial: NDC 65219-622-02 (Single Vial) NDC 65219-622-10 (Unit of 10) 20 mL vial: NDC 65219-624-04 (Single Vial) NDC 65219-624-20 (Unit of 10)	Fresenius Kabi USA, LLC	Fresenius Kabi Canada Ltd.

For additional information on Fresenius Kabi's US-authorized Acyclovir Injection, USP, the US Prescribing Information is available on the Fresenius Kabi Canada Ltd. website for reference by healthcare professionals:

- English version: https://www.fresenius-kabi.com/en-ca/news/importation-of-fresenius-kabi-s-us-authorized-acyclovir-injectio
- French-translated version: https://www.fresenius-kabi.com/fr-ca/news/importation-of-fresenius-kabi-s-us-authorized-acyclovir-injectio

Healthcare professionals are advised that aspects of the product labels and packaging of the US-authorized product may differ from the marketed Acyclovir Sodium Injection products in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The US-authorized product labels (see Appendix) are in English-only and do not include French text.

Additionally, the US-authorized product does not have a Drug Identification Number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker is recommended to enable barcode scanning and allow proper identification of the product being dispensed and administered. It is the responsibility of the receiving organization to create this sticker.

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Reporting adverse drug reactions

Adverse drug reactions associated with the use of US-authorized Acyclovir Injection, USP should be reported to Fresenius Kabi Canada Ltd. or to Health Canada. Refer to below for contact information.

Fresenius Kabi Canada Ltd.
165 Galaxy Blvd., Suite 100, Toronto, ON, M9W 0C8, Canada
Phone: 1-877-779-7760
Fax: 1-844-605-4465
E-mail: Canada_Vigilance@fresenius-kabi.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

Questions or concerns

For questions or concerns about US-authorized Acyclovir Injection, USP, please contact Fresenius Kabi Canada Ltd. at Canada_medinfo@fresenius-kabi.com OR by phone at 1-877-779-7760.

Signed by:
Prachi Chandel
Signer Name: Prachi Chandel
Signing Reason: I approve this document
Signing Time: 02-Sep-25 | 1:10 PM PDT
A1D70C0691214ABC9A8A38206F9F1F46

Original signed by:

Prachi Chandel

Manager and National Safety officer, Vigilance and Medical Affairs

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Appendix

A. Image of US-authorized Acyclovir Injection, USP, Vial (NDC 65219-622-02) in a 10 mL clear, tubular glass vial (NDC 65219-624-04) in a 20 mL clear, tubular glass vial

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B. US-authorized Acyclovir Injection, USP, Vial Label Text

(NDC 65219-622-02) in a 10 mL clear, tubular glass vial

500mg/10mL

NDC 65219-622-02 622010

Acyclovir
Injection, USP

500 mg per 10 mL*
(50 mg per mL)
For IV Infusion Only
MUST BE DILUTED
PRIOR TO USE

Rx only

10 mL Single Dose Vial
Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium equivalent to 50 mg acyclovir.
Usual Dosage : See insert.
DILUTE TO 7 MG/ML OR LOWER PRIOR TO INFUSION. See insert for additional dilution instructions.
Store at 20 °C to 25 °C (68 °F to 77 °F) [see USP Controlled Room Temperature].
Discard Unused Portion.
Code No.: HP/Drugs/MB/13/859
Manufactured for: **Fresenius Kabi**
Lake Zurich, IL 60047
Made in India

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C. US-authorized Acyclovir Injection, USP, Vial Label Text

(NDC 65219-624-04) in a 20 mL clear, tubular glass vial

1000 mg/20 mL

NDC 65219-624-04 622020

Acyclovir
injection, USP

1000 mg per 20 mL*
(50 mg per mL)
Pour perfusion IV uniquement
DOIT ÊTRE DILUÉ AVANT UTILISATION

Rx only

20 mL Single Dose Vial
Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium equivalent to 50 mg acyclovir.
Usual Dosage : See insert.
DILUTE TO 7 MG/ML OR LOWER PRIOR TO INFUSION. See insert for additional dilution instructions.
Store at 20 °C to 25 °C (68 °F to 77 °F) [see USP Controlled Room Temperature].
Discard Unused Portion.
Code No.: HP/Drugs/MB/13/859
Manufactured for: **Fresenius Kabi**
Lake Zurich, IL 60047
Made in India

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D. US-authorized Acyclovir Injection, USP, Carton Label Text (NDC 65219-622-10) Unit of 10

500mg/10mL
NDC 65219-622-10 622010
Acyclovir
Injection, USP

500 mg per 10 mL*
(50 mg per mL)
For IV Infusion Only
MUST BE DILUTED PRIOR TO USE

Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium Equivalent to 50 mg acyclovir. The pH of the solution is 10.85 to 11.50.

Rx Only
10 x 10 mL Single Dose Vials

Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium equivalent to 50 mg acyclovir.
Usual Dosage : See insert.
DILUTE TO 7 MG/ML OR LOWER PRIOR TO INFUSION.
See insert for additional dilution instructions.
Store at 20 °C to 25 °C (68 °F to 77 °F) [See USP Controlled Room Temperature].
Discard Unused Portion.
The container closure is not made with natural rubber latex.
Code No.: HP/Drugs/MB/13/859
Manufactured for:
Lake Zurich, IL 60047
Made in India

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E. US-authorized Acyclovir Injection, USP, Carton Label Text

(NDC 65219-624-20) Unit of 10

1000 mg/20 mL

NDC 65219-624-20 622020
Acyclovir
Injection, USP

1000 mg per 20 mL*
(50 mg per mL)
For IV Infusion Only
MUST BE DILUTED PRIOR TO USE

Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium Equivalent to 50 mg acyclovir. The pH of the solution is 10.85 to 11.50.

Rx Only
10 x 20 mL Single Dose Vials

Sterile, Nonpyrogenic
*Each mL contains acyclovir sodium equivalent to 50 mg acyclovir.
Usual Dosage : See insert.
DILUTE TO 7 MG/ML OR LOWER PRIOR TO INFUSION.
See insert for additional dilution instructions.
Store at 20 °C to 25 °C (68 °F to 77 °F) [See USP Controlled Room Temperature].
Discard Unused Portion.
The container closure is not made with natural rubber latex.
Code No.: HP/Drugs/MB/13/859
Manufactured for:
FRESENIUS KABI
Lake Zurich, IL 60047
Made in India