# Importation of Fresenius Kabi's US-authorized Pantoprazole Sodium for Injection, 40 mg per vial due to the current shortage of Canadian-authorized Pantoprazole Sodium for Injection, 40 mg per vial

Fresenius Kabi Canada Ltd.
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Toronto, Ontario M9W 0C8
Canada

11 October 2024

Dear: Group purchasing organizations (GPOs) and health care professionals (physicians, nurses and pharmacists) including Hospital Pharmacists (Hospital Pharmacists: please distribute to all health care practitioners who administer Pantoprazole Sodium for Injection within the hospital).

There is a critical shortage of Pantoprazole Sodium for Injection, 40 mg/vial in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of US-authorized Pantoprazole Sodium for Injection, 40 mg/vial, with English-only labels, by Fresenius Kabi Canada Ltd.

Health Canada has added Fresenius Kabi's US-authorized 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, Pantoprazole Sodium for Injection, 40 mg/vial is indicated for the short-term treatment (up to 7 days) of conditions where a rapid reduction of gastric acid secretion is required, such as the following: reflux esophagitis, in hospitalized patients who cannot tolerate oral medication, and pathological hypersecretion associated with Zollinger-Ellison Syndrome, in hospitalized patients who cannot tolerate oral medication.

The US-authorized Pantoprazole Sodium for Injection product has the **same active ingredient (pantoprazole), strength (40 mg/vial), dosage form (powder for solution) and route of administration (intravenous)** as the Canadian-authorized product from Fresenius Kabi, but **differs with respect to the product composition and product labelling**.

**The US-authorized product can be used in the same manner as the Canadian-authorized product from Fresenius Kabi, taking into account the differences in product composition and differences between the US Prescribing Information and Canadian Product Monograph summarized in the tables below.**

**Health care professionals should refer to the Canadian Product Monograph for Pantoprazole Sodium for Injection, 40 mg/vial (DIN 02352214) available in English and French on the Health Canada Drug Product Database (https://health-products.canada.ca/dpd-bdpp/).**

The Canadian Product Monograph contains information on the appropriate use of the product, including the:

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

Please refer to the table below for a comparison of the product compositions for Fresenius Kabi's Canadian-authorized Pantoprazole Sodium for Injection and the US-authorized product:

| | Fresenius Kabi's **US**-authorized Pantoprazole Sodium for Injection | Fresenius Kabi's **Canadian**-authorized Pantoprazole Sodium for Injection |
|---|---|---|
| Composition | Each vial contains 40 mg pantoprazole (as pantoprazole sodium sesquihydrate).<br><br>Non-medicinal ingredients: edetate disodium (1 mg) and sodium hydroxide to adjust pH. | Each vial containing 40 mg pantoprazole (as pantoprazole sodium sesquihydrate).<br><br>Non-medicinal ingredients: 1 mg of edetate tetrasodium, 20.2 mg of mannitol, 7 mg of tromethamine, and water for injection. |

Health care professionals should consider the below key differences between the US Prescribing Information and Canadian Product Monograph of Fresenius Kabi's Pantoprazole Sodium for Injection, 40 mg/vial.

| **Condition** | **US-authorized Pantoprazole Prescribing Information** | **Canadian-authorized Pantoprazole Product Monograph** |
|---|---|---|
| **Indications (Treatment Duration)** | Indicated for hospitalized patients who cannot tolerate oral medication and is indicated for short-term treatment up to 7 to 10 days. | Indicated for hospitalized patients who cannot tolerate oral medication and is indicated for short-term treatment up to 7 days. |
| **Warnings and Precautions** | The US Prescribing Information and Canadian Product Monograph differ in the Warnings and Precautions profile | The US Prescribing Information and Canadian Product Monograph differ in the Warnings and Precautions profile.<br><br>The Canadian Product Monograph additionally includes warnings and precautions for *Clostridium difficile* infection (CDI), carcinogenesis and mutagenesis, co-administration with atazanavir, nelfinavir, and saquinavir, cyanobalamin (vitamin B12) deficiency, severe liver disease, critically ill patients, and renal insufficiency.<br><br>Also, the Canadian Product Monograph includes specific |

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|---|---|---|
| | | precautions that pantoprazole should not be administered to pregnant women or nursing mothers unless the expected benefits outweigh the risks to the fetus or infants, and for geriatric populations related to the risk of osteoporosis-related fractures. |
| **Adverse Reactions** | The US Prescribing Information and Canadian Product Monograph differ in the adverse reaction profile | The US Prescribing Information and Canadian Product Monograph differ in the adverse reaction profile |
| **Dosage and Administration** | The US Prescribing Information and Canadian Product Monograph differ in their recommended administration timing, acceptable time within the reconstituted solutions can be used, volumes for reconstitution, and administration and doses. | The US Prescribing Information and Canadian Product Monograph differ in their recommended administration timing, acceptable time within the reconstituted solutions can be used, volumes for reconstitution, and administration and doses.<br><br>The Canadian Product Monograph also includes information about preparing the intravenous infusions in polyvinyl chloride (PVC) and copolymer of ethylene and propylene (PAB) infusion bags. |

Additional information pertaining to Contraindications, Warnings and Precautions, and Drug Interactions in the US Prescribing Information that is **Not** present in the Canadian Product Monograph:

| **Condition** | **US-authorized Pantoprazole Prescribing Information** |
|---|---|
| **Contraindications** | Pantoprazole sodium for injection is contraindicated in patients with known hypersensitivity reactions including anaphylaxis to the formulation or any substituted benzimidazole. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute tubulointerstitial nephritis, and urticaria |
| **Warnings and Precautions** | • Interference with Investigations for Neuroendocrine Tumors: Health care providers should temporarily stop pantoprazole sodium for injection treatment at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial tests are performed (e.g., for monitoring), the same commercial laboratory should be used for testing, as reference ranges between test may vary.<br>• Interference with Urine Screen for THC: Pantoprazole sodium may produce false-positive urine screen for THC (tetrahydrocannabinol). |
| **Drug Interactions** | • Warfarin: Monitor INR and prothrombin time. Dose adjustment of warfarin may be needed to maintain target INR range. |

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|---|---|
| | • Methotrexate: A temporary withdrawal of pantoprazole sodium for injection may be considered in some patients receiving high-dose methotrexate.<br>• Drugs Dependent on Gastric pH for absorption (e.g. iron salts, erlotinib, dasatinib, mycophenolate mofetil, ketoconazole/itraconazole): Mycophenolate mofetil (MMF): Co-administration of pantoprazole sodium in healthy subjects and in transplant patients receiving MMF has been reported to reduce the exposure to the active metabolite, mycophenolic acid (MPA), due to a decrease in MMF solubility at an increased gastric pH. The clinical relevance of reduced MPA exposure on organ rejection has not been established in transplant patients receiving pantoprazole sodium for injection and MMF. Use pantoprazole sodium for injection with caution in transplant patients receiving MMF. |

Health care professionals should note the US-authorized Pantoprazole Sodium for Injection is a sterile product. This information is stated in the US Prescribing Information. The outer carton and vial labels of the US-authorized Pantoprazole Sodium for Injection do not state that the product is “sterile”.

**Information on the imported product**

| Brand name | Dosage form, strength and route of administration | Product description and packaging | Country of authorization and identifying code | Labeler Name | DEL holder/ Importer in Canada |
|---|---|---|---|---|---|
| Pantoprazole Sodium for Injection | Powder for injection, 40 mg/vial, intravenous infusion | Each 10 mL vial containing 40 mg pantoprazole (as pantoprazole sodium sesquihydrate) as a lyophilized powder.<br><br>Available in unit of 10 vials. | USA<br><br>NDC 65219-433-15 Unit of 10 vials<br><br>NDC 65219-433-01 Single-Dose Vial | Fresenius Kabi USA, LLC, United States | Fresenius Kabi Canada Ltd. |

Additional information about US-authorized Pantoprazole Sodium for Injection for health care professionals is available for reference in English only at:

http://products.fresenius-kabi.us/product-394.html

Images of the US-authorized product can be found in the Appendix.

Health care professionals are advised that aspects of the inner and outer labels and packaging of the US-authorized product may differ from marketed Pantoprazole Sodium for Injection, 40 mg/vial 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 does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

**Reporting adverse drug reactions**

Adverse drug reactions associated with the use of Pantoprazole Sodium for Injection should be reported to Fresenius Kabi Canada Limited by calling 1-877-779-7760 or emailing Canada_Vigilance@fresenius-kabi.com, or to Health Canada at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html or by calling toll-free at 1-866-234-2345.

**Questions or concerns**

For questions or concerns about US-authorized Pantoprazole Sodium for Injection, please contact:

Fresenius Kabi Canada Limited by calling 1-877-779-7760 or emailing Canada_Medinfo@fresenius-kabi.com.

**Original signed by:**

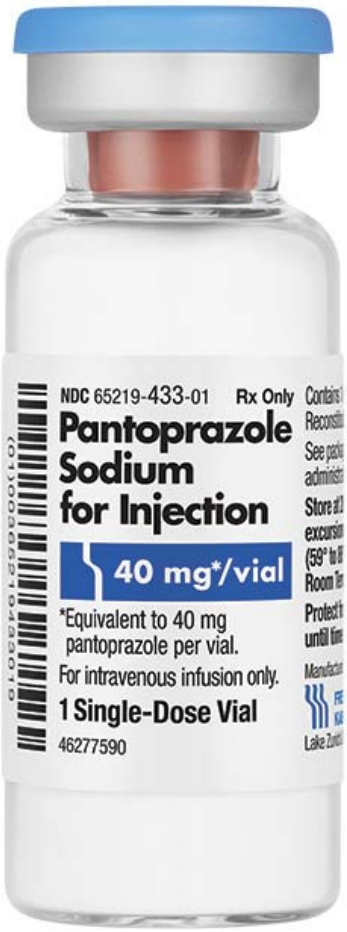
DocuSigned by:
Prachi Chandel
A1D70C0691214AB...

Prachi Chandel
National Safety Officer, Manager, Vigilance and Medical
Fresenius Kabi Canada Ltd.165 Galaxy Blvd, Suite 100
Toronto, Ontario M9W 0C8, Canada

## Appendix

## Images of Fresenius Kabi's US-authorized Pantoprazole Sodium for Injection, 40 mg/vial

## US Vial



US Vial Label:

NDC 65219-433-01, Single-Dose Vial

French Translation of US Vial Label Text:

NDC 65219-433-01 Rx seulement

Pantoprazole sodique pour injection

40 mg*/fiole

*Équivalant à 40 mg
de pantoprazole par fiole.
Pour perfusion intraveineuse seulement.
1 fiole à dose unique
46277590

Contient 1 mg d'édétate disodique.
Reconstitution requise.
Voir le dépliant d'accompagnement pour la posologie et l'administration.

Conserver entre 20° et 25 °C (68° et 77 °F); excursions permises entre 15° et 30 °C (59° et 86 °F) [voir les Directives USP de conservation à température ambiante contrôlée].
Protéger de la lumière. Conserver la fiole dans sa boîte jusqu'au moment de l'utilisation.
Fabriqué pour :
Fresenius Kabi
Lake Zurich, IL 60047

02/2021
LOT: / EXP:

US Package Label:

NDC 65219-433-15, Unit of 10 Vials

French Translation of US Package Label Text:

**PRINCIPAL DISPLAY PANEL / PANNEAU D'AFFICHAGE PRINCIPAL**

**NDC** 65219-433-15

**Pantoprazole sodique pour injection**

40 mg*/fiole

*Équivalant à 40 mg de pantoprazole par fiole.

Rx seulement

**No filter required / Aucun filtre requis**

Pour perfusion intraveineuse seulement

Contient 1 mg d'édétate disodique.

**10 fioles à dose unique**

**SIDE PANEL / PANNEAU LATÉRAL**

Le pantoprazole sodique pour injection est destiné à l'administration intraveineuse uniquement.

Entreposer entre 20 °C et 25 °C (68 à 77 °F); excursions permises entre 15 et 30 °C (59 et 86 °F) [voir les Directives USP de conservation à température ambiante contrôlée].

Reconstitution requise.

Protéger les fioles de la lumière : les conserver dans leur boîte jusqu'au moment de l'utilisation.

Voir le dépliant d'accompagnement pour la posologie et l'administration.

CONTIENT :

10 fioles de pantoprazole sodique pour injection et 1 exemplaire du dépliant d'accompagnement.

Fabriqué pour :

Fresenius Kabi

Lake Zurich, IL 60047

621819

46282213

Produit de l'Inde

02/2021

www.fresenius-kabi.com/us