Importation of Fresenius Kabi's US-authorized Moxifloxacin Injection, 400 mg per 250 mL (1.6 mg per mL), 250 mL ready-to-use, single-dose freeflex® bag due to the current shortage of Canadian authorized Moxifloxacin Injection, 400 mg per 250 mL

2024/05/31

Audience
Dear: Group purchasing organizations (GPOs) and healthcare professionals (physicians, nurses and pharmacists) including Hospital Pharmacists (Hospital Pharmacists: please distribute to all Healthcare Practitioners who administer Moxifloxacin Injection within the hospital).

Key messages
There is a critical shortage of Moxifloxacin Injection in Canada. Given the medical necessity of Moxifloxacin Injection and in order to help mitigate the current shortage, Health Canada has permitted the exceptional, temporary importation and sale of US-authorized Moxifloxacin Injection with English-only labels, by Fresenius Kabi and has added this 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).

- Both Fresenius Kabi's Canadian-authorized Moxifloxacin Injection and Fresenius Kabi's US-authorized Moxifloxacin Injection are indicated for the treatment of adults (≥ 18 years of age) with bacterial infections caused by designated, susceptible microorganisms. Please refer to the Canadian Product Monograph for indications authorized in Canada.

- Both Fresenius Kabi's Canadian-authorized Moxifloxacin Injection and Fresenius Kabi's US-authorized Moxifloxacin Injection are a sterile solution for infusion in a ready-to-use, single-dose flexible bag intended for intravenous (IV) infusion only.

  The formulation is the same for both Fresenius Kabi's Canadian-authorized Moxifloxacin Injection and Fresenius Kabi's US-authorized Moxifloxacin Injection.

Please refer to the table below for details.

	Fresenius Kabi's **Canadian**-authorized Moxifloxacin Injection	Fresenius Kabi's **US**-authorized Moxifloxacin Injection
Composition	Each 250 mL contains: 400 mg moxifloxacin equivalent to 437.5 mg of moxifloxacin hydrochloride, sodium acetate-trihydrate, disodium sulfate, sulfuric acid (for pH adjustment), and water for injection.	Each 250 mL contains: 400 mg moxifloxacin as hydrochloride, sodium acetate trihydrate, disodium sulphate (sodium sulphate anhydrous), sulfuric acid for pH adjustment and water for injection.

- Healthcare Professionals are advised that:
  - For information on appropriate use, including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, storage conditions and handling instructions, Healthcare Professionals should refer to the Canadian Product Monograph (CPM).

    CPM English version: https://www.fresenius-kabi.com/en-ca/documents/Moxifloxacin-PM-021821-ENG.pdf

    CPM French-translated version: https://www.fresenius-kabi.com/fr-ca/documents/Moxifloxacin-PM-FRE-v7.0-042020.pdf

  - **For reference, the USPI can be found at the following link:**

  - http://products.fresenius-kabi.us/product-293.html

  - US-authorized and Canadian authorized Moxifloxacin Injection may differ from one another as noted above. US-authorized product does not have a Drug Identification

Number (DIN) and the barcode may not scan in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being used. Proper selection of the intended product must be confirmed to avoid confusion with other products and prevent medication errors.

Information on the imported product

Brand Name	Dosage Form, Strength, and Route of Administration	Product Description and Packaging	Country of Authorization and Identifying Code	Authorization Holder	Importer in Canada
Moxifloxacin Injection	Intravenous solution, 400 mg/250 mL (1.6 mg per mL), Intravenous infusion only	Intravenous infusion: ready-to-use 250 mL solution in 300 mL polyolefin (freeflex®) latex-free flexible bags containing 400 mg of moxifloxacin (as hydrochloride), single use.	USA NDC 63323-850-74 (package) NDC 63323-850-04 (single bag)	Fresenius Kabi USA, LLC, United States	Fresenius Kabi Canada Ltd.

Additional information for Healthcare Professionals

- The key formulation and labelling characteristics of Fresenius Kabi's US-authorized Moxifloxacin Injection are indicated in the table below:

Product Name	**Moxifloxacin Injection**
Active Substance	Moxifloxacin Hydrochloride
Dosage Form	Sterile solution
Concentration	**400 mg Moxifloxacin per 250 mL** **(1.6 mg Moxifloxacin per mL)**
Packaging Format	Freeflex® flexible bag
Overfill	Fresenius Kabi's US-authorized Moxifloxacin Injection bag has an overfill which is greater than the overfill in Fresenius Kabi's Canadian-authorized Moxifloxacin Injection. This overfill is a minor manufacturing variance in the products. **PLEASE NOTE**: All health care professionals and/or any other hospital personnel should adhere to appropriate dosing protocols and must verify and administer the correct dose and volume to patients.
Storage	Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature] DO NOT REFRIGERATE – PRODUCT PRECIPITATES UPON REFRIGERATION. Avoid excessive heat. Protect from freezing.
Other labelling characteristics	RETAIN IN OVERWRAP TO PROTECT FROM LIGHT. Use unit promptly when pouch is opened. The overwrap is a moisture barrier and is heat sterilized. The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.
Market Authorization Holder	Fresenius Kabi USA, LLC, United States

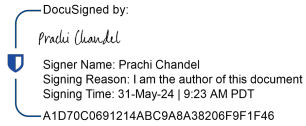
- Infuse over 60 minutes.
- Single-dose only – discard unused portion.
- Do not admix with other drugs or additives.
- No further dilution is necessary.
- Product should be inspected visually for particulate matter and discoloration prior to administration.
- Fresenius Kabi's US-authorized Moxifloxacin Injection is labelled in English only. The French-translated text of the inner and outer labels can be found in the appendices below.

Reporting adverse drug reactions

- Adverse drug reactions associated with the use of Moxifloxacin Injection 400 mg / 250 mL (1.6 mg / mL), USP in patients 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 Moxifloxacin Injection 400 mg / 250 mL (1.6 mg / mL), USP, please contact
Fresenius Kabi Canada Limited by calling 1-877-779-7760 or emailing
Canada_Medinfo@fresenius-kabi.com



Original signed by:

Prachi Chandel
National Safety Officer, Manager, Vigilance and Medical
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Appendices

Images of Fresenius Kabi's US-authorized Moxifloxacin Injection
400 mg per 250 mL (1.6 mg per mL), 250 mL ready-to-use, single-dose freeflex® bag

US Single Bag Label:

NDC 63323-850-04 ; 250 mL fill in a 300 mL freeflex® Bag

US Package Bag Label:

NDC 63323-850-74; Package of 12 freeflex® bags

US Single Bag Outer Wrap Label:

NDC 63323-850-04 ; 250 mL fill in a 300 mL freeflex® Bag

US Package Outer Wrap Label:

NDC 63323-850-74; Package of 12 freeflex® bags

Labels

US Single Bag Inner Label:

French Translation of US Single Bag Inner Label Text:

Bag Label - French

NDC 63323-850-04 / 63323-850-74 850174

Moxifloxacine injectable
400 mg par 250 mL
(1,6 mg par mL)

Pour perfusion intraveineuse

Rx seulement

Utiliser immédiatement une fois retiré du suremballage. Perfuser pendant 60 minutes.

Chaque 250 mL contient : 400 mg de moxifloxacine équivalant à 437,5 mg de chlorhydrate de moxifloxacine, de l'acétate de sodium trihydraté, du sulfate disodique et de l'acide sulfurique (pour l'ajustement du pH) dans de l'eau pour injection.

pH : 5,0 – 6,0.

Dose unique seulement - Jeter toute portion inutilisée.

Posologie habituelle chez l'adulte : voir le feuillet d'emballage

Ne pas mélanger avec d'autres médicaments ou additifs.

Aucune autre dilution n'est nécessaire.

NE PAS RÉFRIGÉRER – Le produit forme des précipités sous réfrigération.

Le dispositif de fermeture du contenant n'est pas fait de latex de caoutchouc naturel.

Sans PVC, sans DEHP, stérile

Fabriqué pour Fresenius Kabi, Lake Zurich, IL 60047

Fabriqué en Norvège

Lot: Exp:

US Single Bag Outer Label:

French Translation of US Single Bag Outer Label Text:

Overwrap Label - French

NDC 63323-850-04 / 63323-850-74 850174

Moxifloxacine injectable
400 mg par 250 mL
(1,6 mg par mL)

Pour perfusion intraveineuse

Rx seulement

LAISSER LE SAC DANS LE SUREMBALLAGE JUSQU'À UTILISATION. PERFUSER PENDANT 60 MINUTES.

Chaque 250 mL contient: 400 mg de moxifloxacine équivalant à 437,5 mg de chlorhydrate de moxifloxacine, de l'acétate de sodium trihydraté, du sulfate disodique et de l'acide sulfurique (pour l'ajustement du pH) dans de l'eau pour injection. pH : 5,0 – 6,0.

Dose unique seulement - Jeter toute portion inutilisée.

Posologie habituelle chez l'adulte : voir le feuillet d'emballage.

Ne pas mélanger avec d'autres médicaments ou additifs. Aucune autre dilution n'est nécessaire. Le suremballage constitue une barrière contre l'humidité et est stérilisé à la chaleur. Utiliser rapidement une fois le sac ouvert.

Conserver entre 20 °C et 25 °C (68 °F et 77 °F) [Voir les directives USP de conservation à température ambiante contrôlée].

NE PAS RÉFRIGÉRER – LE PRODUIT FORME DES PRÉCIPITÉS SOUS RÉFRIGÉRATION.

Éviter la chaleur excessive. Protéger du gel.

Le dispositif de fermeture du contenant n'est pas fait de latex de caoutchouc naturel. Sans PVC, sans DEHP, stérile.

Fabriqué pour Fresenius Kabi, Lake Zurich, IL 60047

Fabriqué en Norvège

Lot: Exp: