



November 29th, 2021

## Expiry Date Extension of Moxifloxacin Injection 400 mg / 250 mL (1.6 mg/mL) in 300 mL freeflex® bags (Product Code: ABU0422), Lot: 12NKU90 and Lot: 12NKU91

Dear Valued Customer,

Fresenius Kabi Canada is currently experiencing supply limitations for Moxifloxacin Injection. In consultation with Health Canada, given the medical necessity of this product and in order to mitigate a shortage, Fresenius Kabi Canada is hereby **extending the expiry date of two lots of Moxifloxacin Injection by an additional 6 months on an exceptional basis** (refer to the table below):

DIN	Product Code	Product Description	Lot	Printed Expiry Date	Expiry Date Extended Until
02433087	ABU0422	Moxifloxacin Injection 400 mg / 250 mL (1.6 mg/mL) in 300 mL freeflex® bags	12NKU90	10/31/2021	04/30/2022
			12NKU91	10/31/2021	04/30/2022

As per the Canadian Product Monograph, Moxifloxacin Injection is indicated for the treatment of adults ( $\geq$  18 years of age) with the following bacterial infections caused by susceptible strains of the designated microorganisms for which treatment is appropriate.

Multi-Drug Resistant *Streptococcus pneumoniae* (MDRSP) are strains resistant to two or more of the following antibiotics: penicillin (MIC ≥2 mcg/mL), 2nd generation cephalosporins (e.g., cefuroxime axetil), macrolides, tetracyclines, and trimethoprim/sulfamethoxazole.

Fresenius Kabi Canada provided data supporting the extension of the expiry date to Health Canada. Based on the review of the data provided, Health Canada had no objection to extending the expiry date for lot 12NKU90 and lot 12NKU91 of Moxifloxacin Injection (DIN 02433087) by an additional 6 months beyond the printed expiry date; the extension of the expiry date will have **no impact on product quality or patient safety**.

Customers can use the product lots indicated above **until April 30, 2022**. An image of the product can be found below.





Fresenius Kabi Canada Ltd.

Moxifloxacin Exceptional Expiry Date Extension



Adverse drug reactions associated with the use of Moxifloxacin Injection should be reported to Fresenius Kabi Canada Ltd. or to Health Canada.

## Fresenius Kabi Canada Ltd.

E-mail: Canada Vigilance@fresenius-kabi.com

Telephone: 1-877-779-7760

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 for information on how to report online, by mail or by fax: <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>

Do not hesitate to contact Fresenius Kabi should any questions arise with respect to this customer notification. Inquiries and questions can be addressed to Customer Service at 1-877-821-7724 or to customer complaints at <a href="mailto:Canada Product Complaints@Fresenius-Kabi.com">Complaints@Fresenius-Kabi.com</a>.

A copy of this customer notification can be found on the Fresenius Kabi Canada website at <a href="https://www.fresenius-kabi.com/en-ca/">https://www.fresenius-kabi.com/en-ca/</a>

Regards,

Anabela Costa Director, Quality Fresenius Kabi Canada Ltd.

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