

STERIMAX

2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

Tel.: 905-890-0661, 1-800-881-3550 • Fax: 905-890-0508, 1-877-546-7667 • Web: www.sterimaxinc.com

Importation of US-labelled Rifabutin Capsules, USP due to the current shortage of Canadian-authorized MYCOBUTIN (rifabutin) Capsules

Date: 31 December 2025

Dear Healthcare professionals (physicians, nurses, pharmacists), wholesalers, HealthPro and Medbuy GPO members,

There is a critical shortage of MYCOBUTIN (rifabutin) capsules in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Novitium Pharma LLC's US-labelled Rifabutin Capsules, USP with English-only labels, by SteriMax Inc.

Health Canada has accepted the addition of Rifabutin Capsules, USP 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) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>).

In Canada, MYCOBUTIN (rifabutin) capsules, 150mg is a prescription drug indicated for the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced HIV infection. To reduce the development of drug-resistant bacteria and maintain the effectiveness of MYCOBUTIN and other antibacterial drugs, MYCOBUTIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

The US-labelled product has the **same active ingredient, strength (150 mg) and route of administration (oral) as the Canadian-authorized product**. The product, however, differs in the following ways:

Healthcare professionals are advised of the following:

- The US-labelled product can be used in the same manner as the Canadian-authorized product.
- **Healthcare professionals should refer to the Canadian Product Monograph for MYCOBUTIN (rifabutin) available in English and French on the Health Canada [Drug Product Database](https://drugproductdatabase.ca/dpd-bdpp/?lang=eng) ([https://health-products.canada.ca/dpd-bdpp/?lang=eng](https://drugproductdatabase.ca/dpd-bdpp/?lang=eng))** The Canadian Product Monograph in the database contain information on the appropriate use of the product, including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.
- Consistent with the dosing instructions in the Canadian Product Monograph for MYCOBUTIN (rifabutin), **the recommended dose of 300mg once daily or one capsule of 150mg twice a day with food.**
- Healthcare professionals responsible for dispensing of the US-labelled product are advised to counsel patients that the US-labelled product is in a different colored capsules with imprinted text on capsule's cap and body but contains the same active ingredient as the Canadian-authorized product.

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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	Authorization holder	DEL holder/ Importer in Canada
Rifabutin Capsules, USP	Capsule, 150mg, Oral	Cap: Maroon colored with imprinted as 041 with black ink Body: Maroon colored with imprinted Novitium 150mg (150mg under Novitium) with black ink Available in a bottle of 100 capsules	United States NDC 70954-041-10	ANI Pharmaceuticals, Inc. 210 Main Street West, Baudette, MN, 56623	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information about US-labelled Rifabutin Capsules, USP for healthcare professionals is available for reference in the English US Prescribing Information at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=baf8ec98-bd0c-4b87-a7ee-813335431b89>.

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

Healthcare professionals are advised that aspects of the product labels and packaging of the US-labelled product may differ from the Canadian-authorized rifabutin capsules. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The US-labelled product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated barcode 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 US-labelled Rifabutin capsules, USP, 150mg should be reported to SteriMax Inc. or to [Health Canada](#):

SteriMax Inc., 2770, Portland Drive, Oakville, ON, L6H 6R4
 Phone: +1-800-881-3550
 Fax: +1-877-546-7667
 E-mail: py@sterimaxinc.com

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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) (<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-labelled Rifabutin capsules, USP, 150mg., please contact SteriMax Inc. at medinfo@sterimaxinc.com OR visit [SteriMax website](https://sterimaxinc.com/contact-us/) (<https://sterimaxinc.com/contact-us/>).

Appendices:

Appendix 01 – Product and bottle image of US-labelled Rifabutin capsules, USP, 150mg.

Appendix 02 – Image of the US outer bottle label: NDC 70954-041-10: Rifabutin capsules, USP, 150mg.

Original signed by

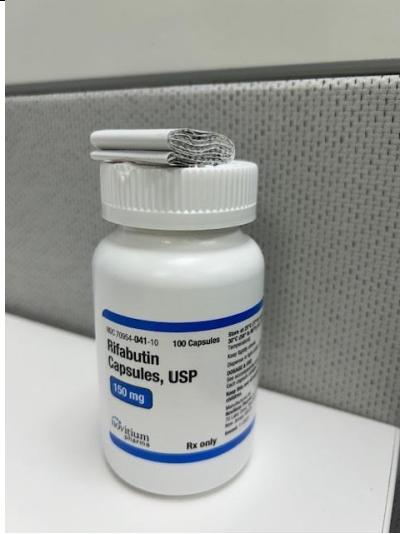
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Ritesh Acharya, M. Pharm.
Chief Scientific Officer,
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Tel.: 905-890-0661, 1-800-881-3550 • Fax: 905-890-0508, 1-877-546-7667 • Web: www.sterimaxinc.com**Appendix 01 – Product and bottle images of US-labelled Rifabutin capsules, USP, 150mg:**

Product description	Product image	Bottle image
NDC 70954-041-10: Rifabutin Capsules, USP, 150mg. Maroon Cap/Maroon Body Hard Gelatin Capsules imprinted with black ink as 041 on cap and Novitium 150 mg (150 mg under Novitium) on body, filled with red-violet powder.		

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- NDC 70954-041-10: Rifabutin capsules, USP, 150mg.

