



## Importation of US-labelled REVATIO® (sildenafil) injection due to the current shortage of Canadian-authorized REVATIO®

**MYLAN PHARMACEUTICALS ULC and BGP PHARMA ULC, both operating as VIATRIS CANADA**

85 Advance Road  
Etobicoke, Ontario Canada  
M8Z 2S9

*May 14 2026*

Dear Wholesalers, Healthcare Professionals and Pharmacists;

There is a critical shortage of Sildenafil Injection in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Viatris Specialty LLC's US-labelled REVATIO® (sildenafil) injection, with English-only labels, by Mylan Pharmaceuticals ULC and BGP Pharma ULC, both operating as Viatris Canada.

Health Canada has accepted the addition of Viatris Canada's product to the [List of drugs for exceptional importation and sale - Canada.ca](http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html) [www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html].

In Canada, REVATIO® (sildenafil) injection is indicated for the continued treatment of patients with pulmonary arterial hypertension who are currently prescribed oral REVATIO® and who are temporarily unable to take oral medication.

The US-labelled product has the **same active ingredient (sildenafil), strength, dosage form, route of administration, product formulation, and volume** as the Canadian-authorized product marketed by BGP Pharma ULC (DIN 02341611). The products, however, **differ with respect to 1) the indicated patient population, as the foreign product is authorized for use in the pediatric population, whereas the use of REVATIO® in pediatric patients has not been assessed by Health Canada, and 2) safety information.**

**The US-labelled product should be used in the same manner as the Canadian-authorized product.**

**Healthcare professionals should refer to the Canadian Product Monograph for REVATIO® (sildenafil) injection, 0.8 mg/mL from BGP Pharma ULC (DIN 02341611), available in English**

and French on the Health Canada [Drug Product Database](http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html) [www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html] for complete instructions on the proper use of this product as approved in Canada, including the approved indication, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

### 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                           |
|------------|--|--|---|------------------------------|--|
| REVATIO®   | Sterile Solution, 0.8 mg/mL<br><br>For intravenous use | Sterile solution, single dose vial<br><br>Each 12.5 mL vial contains 10 mg of Sildenafil (0.8 mg/mL)<br><br>Available in a carton of 1 | USA<br>NDC: 58151-395-31                      | Viatrix Specialty LLC, USA   | Mylan Pharmaceuticals ULC o/a Viatrix Canada |

Additional information about US-labelled REVATIO® (sildenafil) injection for healthcare professionals is available for reference in English only at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3bb9363e-b28d-4019-8aae-539233dca214&type=display>. Images of the US-labelled product can be found in the Appendix below.

Healthcare professionals are advised that aspects of the product labels and packaging of the US-labelled product may differ from the marketed sildenafil injection product in Canada. **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 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 REVATIO® (sildenafil) injection should be reported to Viatris Canada at [1-877-446-3679](tel:1-877-446-3679), or to [Health Canada](http://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) [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-labelled REVATIO® (sildenafil) injection, please contact Viatris Canada at [1-877-446-3679](tel:1-877-446-3679).

### Appendix





Store at controlled room temperature 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Each mL of solution contains 1.124 mg sildenafil citrate, 50.5 mg dextrose and Water for Injection.

**DOSAGE AND USE**

See accompanying prescribing information.

RUPJ395TT1

NDC 58151-395-31  
 Sterile Single-dose Vial **Rx only**  
**Revatio**<sup>®</sup>  
 (sildenafil) Injection  
**10 mg/12.5 mL**  
 (0.8 mg/mL)

For Intravenous Use

Sterile Single-dose Vial, Discard Unused Portion 



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Distributed by:  
**Viatrix Specialty LLC**  
 Morgantown, WV 26505 U.S.A.  
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Lot:

Exp:



Original Signed By:

Bruna Paniccia  
Head of Quality  
Mylan Pharmaceuticals/BGP Pharma ULC