Importation of US-labelled Biltricide® (praziquantel) due to the discontinuation of Canadian-authorized Biltricide® (praziquantel)

September 2025

Dear: Healthcare professionals, including infectious disease and tropical medicine specialists, pharmacists and distribution partners

Biltricide® (praziquantal) has been discontinued globally. To help mitigate the discontinuation, Health Canada has permitted the exceptional, temporary importation and sale by Bayer Inc. of Bayer Healthcare Pharmaceuticals Inc.'s US-labelled Biltricide® (praziquantel). This imported product has an English-only label.

Bayer Inc.
Pharmaceuticals Division
2920 Matheson Blvd. East
Mississauga, ON L4W 5R6

Health Canada has accepted the addition of Bayer Healthcare Pharmaceuticals Inc.'s product to the List of drugs for exceptional importation and sale.

In Canada, Biltricide® is indicated for the treatment of infections due to the following species of schistosoma: (*Schistosoma haematobium, Schistosoma japonicum, Schistosoma mansoni, and Schistosoma mekongi*) and the treatment of infections due to the liver flukes *Clonorchis sinensis/Opisthorchis viverrine*.

Considering the limited treatment options for these parasitic infections, we urge all healthcare providers to be mindful of the discontinuation and reserve the use of Biltricide® for potentially life-threatening infections where no alternative treatments are available.

The US-labelled Biltricide® has the **same** active ingredient (praziquantel), product formulation, strength (600 mg), dosage form (tablet), route of administration (oral), fill volume (6 tablets per bottle), and recommended dosage regimen as the Canadian-authorized Biltricide®.

The US-labelled Biltricide®, however, differs from the Canadian-authorized product in terms of indications and packaging format. The US-labelled Biltricide® can be used in the same manner as Canadian-authorized Biltricide®. Healthcare professionals should refer to the Canadian Product Monograph for Biltricide® available in English (https://www.bayer.com/sites/default/files/2020-11/biltricide-pm-en.pdf) and French (https://www.bayer.com/sites/default/files/2020-11/biltricide-pm-fr.pdf) for information on the appropriate use of the product, including the:

- indications
- contraindications
- serious warnings and precautions box
- warnings and precautions
- adverse reactions
- dosage and administration

- storage conditions, **notably protect the product from light and excessive humidity.**

Healthcare professionals are advised that the US-labelled Biltricide® is available in **high-density polyethylene (HPDE) bottles** while the Canadian-authorized Biltricide® is available in **glass bottles.**

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
Biltricide®	Tablet, 600 mg, oral	6 tablets / bottle	United States, Food and Drug Administration, National Drug Code (NDC) 50419-747-0	Bayer HealthCare Pharmaceuticals Inc.	Bayer Inc.

For reference, healthcare professionals can access the US Prescribing Information for US-labelled Biltricide® in English at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018714s020lbl.pdf.

Healthcare professionals are advised that the US-labelled Biltricide® **does not have an outer carton**. Healthcare professionals are also advised that other aspects of the inner label and packaging of the US-labelled Biltricide® may differ from the Biltricide® currently marketed in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The US-labelled Biltricide® does not have a drug identification number (DIN) or a barcode that scans in medication management systems used 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.

The US-labelled Biltricide® will be distributed with the Canadian English and French Patient Medication Information section of the Product Monograph. Please refer to the Appendix for images of the US-labelled Biltricide® packaging.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of Biltricide® should be reported to Bayer Inc. by calling at 1-800-265-7382 or at https://safetrack-public.bayer.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-labelled Biltricide®, please contact Bayer Inc. Medical Information at 1-800-265-7382 or Canada.medinfo@bayer.com.

Sincerely,

Shurjeel Choudhri *BSc(med) MD FRCPC*

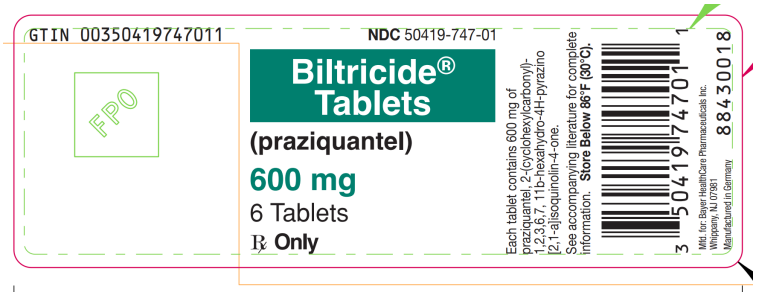
SVP & Head, Medical & Scientific Affairs

Appendix

US-labelled Biltricide® bottle:

US-labelled Biltricide® bottle label:

English text



French text
NDC: 50419-747-01

Biltricide® Comprimés
(praziquantel)
600 mg
6 Comprimés
Rx Seulement

Un comprimé contient 600 mg de praziquantel et (cyclohexylcarbonyl)-2 hexahydro-1,2,3,6,7,1 1 b 4H-pyrazinol[2,1-a] isoquinoléinone-4.

Consulter le document ci-joint pour plus de détails. **Conserver à moins de 30 °C (86 °F).**

Fabriqué pour: Bayer HealthCare Pharmaceuticals Inc.
Whippany, NJ 07981
Fabriqué en Allemagne