



## Importation of Middle Africa-labelled Biltricide® (praziquantel) due to the current shortage of Canadian-authorized Biltricide® (praziquantel)

December 2024

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

There is a critical shortage of Biltricide® (praziquantel) in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Bayer AG's Middle Africa-labelled Biltricide® (praziquantel), that has English and French labels, by Bayer Inc.

Health Canada has accepted the addition of Bayer 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*.

The Middle Africa-labelled Biltricide® has the **same** active ingredient (praziquantel), strength (600 mg), dosage form (tablet), route of administration (oral) and product formulation as Canadian-authorized Biltricide®.

The Middle Africa-labelled Biltricide®, however, differs from the Canadian-authorized product in terms of indications, recommended dosage regimen, and fill volume. The Middle Africa-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 Middle Africa-labelled Biltricide® is available in **bottles of 4 tablets** while the Canadian-authorized Biltricide® is available in **bottles of 6 tablets**.



Bayer Inc.  
Pharmaceuticals Division  
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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
Biltricide®	Tablet, 600 mg, oral	4 tablets / bottle	Benin, 4062/93 Burkina Faso, 005742005XC112000 Cameroon, 92.07.0391 RV Congo, 007-R-92 /M2.22.01/05-113-RVC Cote D'Ivoire, E-95-0070 Gabon, 3712/94/04 Guinea, 50031 Madagascar, 31.1.1.062 Niger, 72494 Senegal, 1474 Chad, 96 500 802 Togo, SP.TG. 1371	Bayer AG	Bayer Inc.

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the Middle Africa-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 Middle Africa-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 Middle-Africa-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 Middle Africa-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 Middle Africa-labelled Biltricide<sup>®</sup>, please contact Bayer Inc. Medical Information at 1-800-265-7382 or [Canada.medinfo@bayer.com](mailto:Canada.medinfo@bayer.com).

Sincerely,

Shurjeel Choudhri *BSc(med) MD FRCPC*

SVP & Head, Medical & Scientific Affairs



## Appendix

### Middle Africa-labelled Biltricide® carton:



### Middle Africa-labelled Biltricide® bottle:





### Middle Africa-labelled Biltricide® carton label:



### Middle Africa-labelled Biltricide® bottle label:

