

PART III: CONSUMER INFORMATION

PrBILTRICIDE®

(Praziquantel) Tablets

This leaflet is Part 3 of a three-part "Product Monograph" designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BILTRICIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

BILTRICIDE (praziquantel) can only be obtained with a prescription from your doctor. This drug has been prescribed by your doctor to treat the infection you have that is caused by worms and/or liver flukes. Do not give this medicine to other people.

What it does:

BILTRICIDE interferes with the action of the cell membrane, leading to parasite death and reduction of the infection.

When it should not be used:

Do not use BILTRICIDE if you:

- took it before and had an allergic reaction to it (see "What the nonmedicinal ingredients are")
- have a parasitic worm infection of the eye (ocular cysticercosis)
- are taking rifampin at the same time because the amount of BILTRICIDE in your body may be lowered below the level required to treat your infection.

What the medicinal ingredient is:

praziquantel

What the nonmedicinal ingredients are:

Corn starch, Magnesium stearate, Microcrystalline cellulose, Polyvidone 25, Sodium lauryl sulphate, Polyethylene glycol 4000, Methylhydroxypropyl-cellulose, Titanium dioxide

What dosage forms it comes in:

BILTRICIDE is supplied as a 600 mg white, oblong tablet with three notches. It is marked BAYER on one side and LG on the other. When broken, each of the four pieces that result contains 150 mg of active

ingredient (praziquantel). This allows your doctor to easily adjust the dose depending on your weight.

Pieces are broken off by pressing the notch with your thumbnails. If only one quarter of a tablet is required, this is best achieved by breaking the tablet from the outer end.

WARNINGS AND PRECAUTIONS

Tell your doctor about all the medications you are taking, including prescription, non-prescription drugs and natural health products.

BEFORE you use BILTRICIDE talk to your doctor or pharmacist if you have or have had any of the following conditions:

- you are pregnant or planning to become pregnant
- you are breastfeeding or planning to breastfeed. BILTRICIDE is excreted in human breast milk. Discuss with your doctor if breastfeeding is right for your infant.
- you have a history of epilepsy
- you have problems with your kidney or liver function
- you have problems with your heart

The safety and effectiveness of BILTRICIDE in children under 4 years of age has not been established.

You should not drive or operate machinery on the day of your treatment and during the next 24 hours as your reflexes may be impaired.

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor before using any of the following drugs which may interact with BILTRICIDE. Your doctor may suggest alternate medications or a change in dosage:

- Albendazole
- Anticonvulsants (phenytoin, fosphenytoin, carbamazepine and phenobarbital)
- Anti-fungal agents (miconazole, ketoconazole, itraconazole)
- Cimetidine
- Chloroquine
- Dexamethasone
- Erythromycin

Glucose and bicarbonate can cause a decrease in BILTRICIDE levels in your blood.

Avoid eating grapefruit or drinking grapefruit juice while you are using this medicine.

Tell your doctor or pharmacist if you are taking or have recently taken any other medication, including medications obtained without a prescription as well as vitamins and herbal supplements, such as St. John's Wort (*Hypericum perforatum*).

- hives (urticaria)
- loss of appetite
- muscle pain
- nausea
- rash
- tiredness
- vomiting
- weakness

PROPER USE OF THIS MEDICATION

Usual dose

The dose depends on your weight. You must take the medicine exactly as it is prescribed by your doctor, as a one day treatment. If you are not sure how many tablets to take or how often to take them, consult your doctor or pharmacist.

You should not change the dose prescribed by your doctor.

The tablets should be swallowed whole with some liquid, preferably during or after meals. Keeping the tablets (and pieces of the tablets) in your mouth may release a bitter taste which can cause you to gag or vomit.

The time between doses should be at least 4 hours and not more than 6 hours.

Overdose

In case of drug overdose, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

Often it is hard to tell if the side effects are due to the medicine or the infection itself. If you are concerned about how you are feeling after you take the medicine, or if you feel noticeably worse, contact your doctor or pharmacist as soon as possible.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency	Symptom/ Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Rare	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing,			✓
	Irregular or rapid heartbeat			✓
	Seizures			✓
	Bloody diarrhea	✓		

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

After taking your medicine you may experience some side effects. These vary according to the dose and duration of your treatment. They also depend on the type of infection you have, how long you have had the infection, and where in your body the infection is. The side effects, if there are any, are most often one or more of the following:

- abdominal pain
- dizziness
- drowsiness
- diarrhea
- fever
- headache

This is not a complete list of side effects. For any unexpected effects while taking BILTRICIDE, contact your doctor or pharmacist.

HOW TO STORE IT

Store this medicine at room temperature below 30°C. Keep this and all medicine in a safe place out of the reach and sight of children. Do not store in a damp place and keep away from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:

Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and e-mail address.

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Last revised: May 9, 2017

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