

Applicant: Bayer (Pty) Ltd
Product name: BILTRICIDE
Dosage form: Film-coated tablets
Strength: 600 mg praziquantel

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BILTRICIDE 600 mg Film-coated Tablets
Praziquantel
Sugar free

Read all of this leaflet carefully before you start taking BILTRICIDE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- BILTRICIDE has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

1. What BILTRICIDE is and what it is used for.
2. What you need to know before you take BILTRICIDE.
3. How to take BILTRICIDE.
4. Possible side effects.
5. How to store BILTRICIDE.
6. Contents of the pack and other information.

1. What BILTRICIDE is and what it is used for

BILTRICIDE contains the active ingredient, praziquantel which belongs to the group of antiparasitic medicines (anthelmintics).

It is used for the treatment of parasitic worm infections caused mainly by cestodes (tapeworms) or trematodes (flatworms).

BILTRICIDE kills the worms by causing a rapid contraction and paralysis of the parasite; it also stops the parasite from being able to absorb and use sugars. The parasite then disintegrates with the help of the white blood cells and is passed from the body.

BILTRICIDE is used for the treatment of parasitic infections in humans caused by blood flukes (worms), (schistosoma infections e.g. due to *S. haematobium*, *S. mansoni*).

2. What you need to know before you take BILTRICIDE

Do not take BILTRICIDE

- if you are allergic (hypersensitive) to praziquantel, or any other ingredients of BILTRICIDE listed in section 6.
- during the first trimester of pregnancy.

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- if your eyes are infected by larvae of the pork tapeworm (*intraocular cysticercosis*), since parasite destruction within the eye may cause irreversible lesions.
- if you concomitantly take medicines whose active ingredient lowers the blood levels of the active ingredient of BILTRICIDE (see section “Other medicines and BILTRICIDE”).

Rifampicin is such a substance which is used as an antibiotic to treat tuberculosis or leprosy.

If you are using this medicine, ask your doctor about switching to another medicine before you take BILTRICIDE. If any of these conditions appear for the first time while using BILTRICIDE, stop taking it at once and consult your doctor.

Warnings and precautions

Take special care with BILTRICIDE:

Tell your doctor if you have or have had any of the following medical conditions:

- any problems with your liver or your spleen, since your doctor may want to hospitalize you while you are taking BILTRICIDE
- any kidney disease that causes you to pass little or no urine
- any heart problems, since your doctor may want to monitor you carefully while you are taking BILTRICIDE
- a history of epilepsy (recurrent fits) and/or other signs of potential central nervous systems involvement such as slightly elevated lesions on or in the skin (*subcutaneous nodules*) as it may worsen the condition.

If BILTRICIDE has been prescribed to you for the treatment of a chronic parasitic infestation caused by blood flukes (schistosomiasis), the use of BILTRICIDE may be associated with deterioration of your medical condition with symptoms similar to an allergic reaction. This can lead to potentially life-threatening events such as lung failure, encephalopathy (disease of the brain), and/or narrowing or blockage of blood vessels in the brain (cerebral vasculitis).

Your doctor may hospitalize you for the duration of the treatment if you got a parasitic worm infection from the constantly infected areas you live in. There is a possibility that you might have more than one condition caused by the worm infection.

Children and adolescents

Safety in children younger than 1(one) year of age has not been established.

Other medicines and BILTRICIDE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). Some medicines:

- can have an influence on the blood levels of BILTRICIDE,
- can stop BILTRICIDE from working properly,

These include

- cimetidine (a medicine used to treat high acid levels in your stomach, reflux and ulcers)
- medicines for treating fungal infections (ketoconazole, itraconazole)
- medicines for treating bacterial infections/ antibiotic (erythromycin, rifampicin)
- medicines to treat HIV infections (efavirenz, ritonavir)
- medicines for treating epilepsy
- dexamethasone (an anti-inflammatory and immunosuppressant)

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You must avoid taking BILTRICIDE together the medicines like rifampicin (used as an antibiotic to treat tuberculosis or leprosy) that increase the metabolic activity of the liver as this may lower the blood levels of the active ingredient of BILTRICIDE.

Efavirenz which is used to treat HIV infections is another medicine that you should avoid taking together with BILTRICIDE.

BILTRICIDE with food and drink

Take BILTRICIDE preferably during or after meals.

Simultaneous consumption of grapefruit juice may lead to increased praziquantel levels.

Pregnancy, Breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BILTRICIDE.

If you are pregnant it is not recommended that you take BILTRICIDE because safety in pregnancy is not established.

The active ingredient is excreted in breast milk of nursing women. It is not known whether an effect is likely to occur in infants. For short-term therapy, you should not breastfeed your baby during the day(s) you take BILTRICIDE and the following 24 hours.

Driving and using machines

You should not drive, cycle or operate machinery on the day(s) of treatment and during the subsequent 24 hours because you may feel tired or dizzy after taking BILTRICIDE.

3. HOW TO TAKE BILTRICIDE

Do not share medicines prescribed for you with any other person.

Always take BILTRICIDE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose prescribed by your doctor is dependent on your bodyweight and/or your diagnosis and may differ from the following generally recommended dose:

The dose for treatment of Schistosomiasis caused by *S. haematobium* and *S. mansoni*: 1 x 40 mg/kg bodyweight or 2 x 20 mg/kg bodyweight as one day treatment.

The tablet can be divided into four parts. Each part of the four segments contains 150 mg of the active ingredient. This allows an easy adjustment of the dosage to your bodyweight.

If your doctor prescribed single daily doses of BILTRICIDE, it is recommended that you take the tablets in the evening.

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If your doctor prescribed several doses of BILTRICIDE a day, the time between you take the doses should be not less than 4 hours and not more than 6 hours.

BILTRICIDE tablets are for oral use. Swallow the tablet as a whole and with some liquid, preferably during or after meals.

If you take more BILTRICIDE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

A fast-acting laxative may be given to you.

If you forget to take BILTRICIDE

Do not take a double dose to make up for forgotten individual doses.

4. Possible Side effects

BILTRICIDE can have side effects.

Not all side effects reported for BILTRICIDE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BILTRICIDE, please consult your health care provider for advice.

The frequent side effects are:

Headache, dizziness, stomach pains, nausea, vomiting, urticaria(hives), fatigue (excessive tiredness), vertigo, somnolence (drowsiness), anorexia, diarrhoea (very rarely bloody diarrhoea), rash, myalgia (muscle pain), asthenia (feeling unwell), fever.

The less frequent side effects are:

Allergic reaction, polyserositis (inflammation of several serous membranes such as the pleura, pericardium, and peritoneum at the same time), eosinophilia (increase in number of disease-fighting white blood cells), seizures, unspecific dysrhythmias(unspecified disturbance in the rate or rhythm of the heartbeat), pruritus (intense itching).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BILTRICIDE.

5. How to store BILTRICIDE

Store at or below 30 °C.

Keep this medicine out of the sight and reach of children.

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6. Contents of the pack and other information

What BILTRICIDE contains

The active ingredient is praziquantel and each film-coated tablet contains 600 mg praziquantel. The other ingredients are hypromellose 15 cp (Hydroxypropylmethylcellulose), macrogol 4000 (Polyethylene glycol 4000), magnesium stearate, maize starch (corn starch), microcrystalline cellulose, povidone, sodium lauryl sulphate, titanium dioxide (E171/C.I. 77891).

What BILTRICIDE looks like and contents of the pack

BILTRICIDE film-coated tablets are oblong and white, marked with LG on the one side and BAYER on the other. The tablet can be divided into four (4) equal segments because of the three score lines.

Each bottle contains 4 or 10 tablets.

Each tin contains 1000 film-coated tablets.

Pack sizes of 4's or 10's or 1000's film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

BAYER (PTY) LTD
(Reg No: 1968/011192/07)
27 Wrench Road
Isando
1609

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