

4. What are the possible side effects?

As for all drugs, people who are sensitive to the ingredients of BIODAZOLE® may experience side effects.

If any of the following occurs, stop taking BIODAZOLE® and IMMEDIATELY inform your doctor or refer to the emergency room of the closest hospital:

- Hives (generally an itchy skin disease)
- Shortness in breath
- Swelling of face, lips, tongue and throat

These are all very serious side effects. If you have experienced any of them, then you're very allergic to BIODAZOLE®. An immediate medical intervention or hospitalization may be necessary. All of these serious side effects are observed considerably rare.

In case you realize any of the following, inform your doctor immediately or refer to the emergency room of the closest hospital:

- Easy bruising or bleeding, excessive weakness
 - Fever, sore throat, severe headache, peeling of the skin and red skin rash
 - Fever with accompanying chilling, body pain and symptoms of flu
- These are all serious side effects. An immediate medical intervention may be necessary. Serious side effects are observed very rare.

In case you realize any of the following, inform your doctor:

- Abdominal pain
- Nausea, vomiting
- Headache, dizziness
- Temporary hair loss

These are mild side effects of BIODAZOLE®.

If you experience any side effect which is not mentioned in this user manual, then inform your doctor or pharmacist.

5. Storage of BIODAZOLE®

Keep BIODAZOLE® out of sight and reach of children and in its package. Store at room temperature below 25°C.

Do not freeze.

Consume in compatible with the expiry date

Do not consume BIODAZOLE® after the expiry date on the package. In case you realize a decomposition of the product and/or a deformation of the package, do not use BIODAZOLE®.

This user manual has been approved on 21/12/2011.

DIRECTIONS FOR USE

BIODAZOLE® suspension 2%

For oral use.

Each 10 ml (1 cup) of suspension contains;

- Active ingredient: 200 mg of albendazole,
- Excipients: Microcrystalline cellulose (E460), sucrose, glycerin (E422), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), carboxymethylcellulose sodium (E466), saccharin sodium (E954), tartarazine (E102), banana extract, polysorbate 60 (E435) and deionized water.

Before using this medicine read this USER MANUAL carefully, since it contains important information for you.

- Keep this user manual. You may need to read it again.
- In case you have additional questions, please consult your doctor or pharmacist.
- This medicine is prescribed personally for you, do not hand it to others.
- While using this drug, in case you visit a doctor or a hospital indicate that you're using this drug.
- Follow the information written in this instruction exactly. Do not take doses of drug higher or lower than recommended.

In this User Manual:

1. What is BIODAZOLE® and what is it used for?
2. Considerations before the use of BIODAZOLE®
3. How to use BIODAZOLE®?
4. What are the possible side effects?
5. Storage of BIODAZOLE®

These headings are available.

1. What is BIODAZOLE® and what is it used for?

BIODAZOLE® suspension is available in 20 and 60 ml of brown bottles, with a PE plastic cap, that contains 200 mg of albendazole per cup and with a 10 ml of plastic spoon cup. BIODAZOLE® is an antihelmintic drug. It prevents larva that has recently come out of egg develop and proliferate in the body. BIODAZOLE® is used in the treatment of certain infections caused by the intestinal worms such as pork tapeworm and hydatid worm. BIODAZOLE® can be used for other purposes which are not mentioned in this user manual.

2. Considerations before the use of BIODAZOLE® DO NOT USE BIODAZOLE® in case of the following circumstances

Do not use it if you're sensitive (allergic) to albendazole or similar drugs such as mebendazole.

USE BIODAZOLE® CAREFULLY in case of the following circumstances

if;

- you have a hepatic problem or abnormal values were determined by the hepatic function tests before,
- BIODAZOLE® may reduce the blood levels of cells that play a role in your body to fight toward infectious agents. This may cause you bleed easily due to any injury and infected by the sick people around you. Therefore, use BIODAZOLE® carefully in case the blood levels of the cells in question are very low. If these warnings apply to you, even in the past, please consult your doctor.

Use of BIODAZOLE® together with food and drink
Take BIODAZOLE® with food to reduce nausea.

Pregnancy

Before using the drug consult your doctor or pharmacist. Do not use BIODAZOLE® if you are pregnant or planning to become pregnant. Use an effective contraceptive method during BIODAZOLE® treatment and the first month after the treatment ends.

During the treatment, if you realize that you're pregnant, consult your doctor or pharmacist immediately.

Lactation

Before using the drug consult your doctor or pharmacist. It's not known whether BIODAZOLE® is excreted in human milk. Since quite a lot of drugs are excreted in human milk, breast-feeding mothers should be careful.

Operating a vehicle and machinery

No effects on operating a vehicle and machinery have been reported.

Important information on certain excipients of BIODAZOLE®

Sucrose:

If you are previously told by your doctor that you're intolerant (sensitive) to some of the sugars, contact your doctor before the use of this medicinal product.

Methyl parahydroxybenzoate and propyl parahydroxybenzoate: They may cause allergic reactions (possibly delayed).

Sodium:

This medicinal product contains less than 1 mmol (23 mg) of sodium in 10 ml (1 cup) of suspension; namely, it basically does not "contain sodium".

Tartrazine:

It may cause allergic reactions.

Concomitant use with other drugs

Concomitant use of BIODAZOLE® with the following drugs may be inconvenient:

- Cimetidine
- Dexamethasone
- Praziquantel
- Theophylline

There may also be other drugs that can interfere with BIODAZOLE®. Do not commence to use a new drug without informing your doctor, including vitamins, minerals, herbal products.

If you're now using or have recently used any drug with or without prescription, please inform your doctor or pharmacist about this.

3. How to use BIODAZOLE®?

Always use the suspension as directed by your physician. General dosing is as follows:

Instructions for appropriate usage and dosing/administration frequency:

Hydatid disease:

For individuals with a body weight of 60 kg or more;
400 mg (2 cups) is administered twice daily with food for 28 days. Then the treatment is discontinued for 14 days. This plan is repeated for 3 times.

For individuals with a body weight of less than 60 kg;
15 mg/kg is administered twice daily with food for 28 days. Then the treatment is discontinued for 14 days. This plan is repeated for 3 times.

Neurocysticercosis:
For individuals with a body weight of 60 kg or more;
400 mg (2 cups) is administered twice daily with food for 8-30 days.
For individuals with a body weight of less than 60 kg;
15 mg/kg is administered twice daily with food for 8-30 days.

Other Helminthiasis Infections:

Dosing scheme for adults:

Ascariasis, Enterobiasis (Oxyuriasis), Hookworm disease (*N. americanus*, *A. duodenale*), Trichuriasis, Trichostrongyliasis: 400 mg of albendazole (2 cups) is administered as a single dose at once. Treatment can be repeated after 3 weeks. Taeniasis (*T. saginata*, *T. solium*) and Strongyloidiasis: 400 mg of albendazole (2 cups) is administered once daily for 3 consecutive days. Treatment can be repeated after 3 weeks.

Capillariasis: 200 mg of albendazole (1 cup) is administered twice daily for 10 days.

Trichinosis: 400 mg of albendazole (2 cups) is administered twice daily for 15 days.

Chlonorchiasis: 400 mg of albendazole (2 cups) is administered once or twice daily for 7 days or 10 mg/kg of albendazole is administered twice daily for 7 days.

Giardiasis: 400 mg of albendazole (2 cups) is administered daily for 3 days.

Route and method of administration:

BIODAZOLE® is for oral use only. Before each use, shake the bottle thoroughly.

Several age groups:

Use in children:

There is a limited experience in children under 6 years.

For neurocysticercosis and hydatid disease, adult dosing scheme is administered.

For the treatment of Ascariasis, Enterobiasis (Oxyuriasis), Hookworm disease (*N. americanus*, *A. duodenale*), Trichuriasis:

- In children up to 2 years of age: 200 mg (1 cup) of albendazole only for once as a single dose. Treatment can be repeated after 3 weeks.

- In children above 2 years of age: Adult dosing scheme is administered.

For the treatment of Taeniasis and Strongyloidiasis:

- In children up to 2 years of age: 200 mg of albendazole (1 cup) is administered once daily for 3 consecutive days. Treatment can be repeated after 3 weeks.

- In children above 2 years of age: Adult dosing scheme is administered.

For the treatment of Capillariasis: 200 mg of albendazole (1 cup) twice daily

For the treatment of Trichostrongyliasis: 400 mg of albendazole (2 cups) as a single dose

Use in elderly:

Same dose for adults can be administered.

Use in special circumstances:

Renal insufficiency:

If you have a renal insufficiency, inform your doctor for dose adjustment.

Hepatic impairment:

If you have a hepatic impairment, inform your doctor for dose adjustment.

If you observe a very potent or weak effect of BIODAZOLE®, talk to your doctor or pharmacist.

In case you've used BIODAZOLE® for more than you should:

In case you've used more BIODAZOLE® than you should, talk to a doctor or a pharmacist.

A supportive and symptomatic treatment is used.

In case you forget to take BIODAZOLE®

Do not worry if you forget to take the drug, take it as soon as you remember.

If timing of the next dose is too soon, wait until then and continue to take the suspension normally.

Do not take double dose to balance the forgotten doses.

The effects that can occur upon discontinuation of BIODAZOLE® treatment

Always take your medicine until the treatment period that your doctor has recommended is completed. Your disease symptoms may get better before the infection is completely improved, in that case do not stop the treatment.

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