PATIENT INFORMATION LEAFLET

BIODAZOLE 400 mg Film Coated Tablet
Oral administration.

Each film coated tablet contains:
- **Drug substance:** 400 mg Albendazole
- **Excipients:** Lactose monohydrate, cellulose (E460), sodium starch glycolate, maize starch, povidone (E1201), sodium lauril sulfate, saccharin sodium (E954), iron oxide red (E172), raspberry flavor, banana flavor, magnesium stearate (E572), polyvinyl alcohol, titanium dioxide (E171), talc (E553b), soya lecithin (E322), xanthan gum (E415), FD&C Blue #2/indigo carmine aluminium lac (E132)

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine, since it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to the doctor or hospital during the usage of this medicine, please tell your doctor that you are using this medicine.*
- *Please exactly follow the instructions written in this leaflet. Do not use **high or low** dose apart from the recommended dose of the medicine.*

In this leaflet:

1. What BIODAZOLE is and what it is used for
2. What you need to know before you take BIODAZOLE
3. How to take BIODAZOLE
4. Possible side effects
5. How to store BIODAZOLE

1. What BIODAZOLE is and what it is used for
ANDAZOL is a film coated tablet containing 400 mg albendazole presented in a blister package of 3 and 60 film coated tablets. Film coated tablets are raspberry and banana flavored, light pink colored, oblong, biconvex and scored on both sides. BIODAZOLE is an anthelmintic medicine. It inhibits growth and multiplication in the body of the newly hatched insect larvae. BIODAZOLE is used to treat certain infections caused by worms such as pork tapeworm and dog tapeworm. BIODAZOLE may also be used for purposes other than those listed in this information leaflet.

2. What you need to know before you take BIODAZOLE

Do not take BIODAZOLE in the following conditions
If you are allergic (hypersensitive) to albendazole or a similar drugs such as mebendazole.

Take BIODAZOLE with special care in the following conditions
- If you have a liver problem or abnormal results that have previously been identified in your liver function tests.
- BIODAZOLE may lower blood levels of cells which are helping your body to fight against infection agents. This may cause you to be susceptible to bleeding owing to any injury whatsoever and may cause you to contract any disease from those around you. Therefore, if blood levels of such cells are very low, take BIODAZOLE with ultimate care.

If these warnings apply to you even for a past time, please consult your doctor.

Taking BIODAZOLE with food and drink
Take BIODAZOLE with food so as to lessen your nausea.

Pregnancy
Ask your doctor or pharmacist for advice before taking this medicine.
If you are pregnant or trying to become pregnant do not use BIODAZOLE.
Use an effective birth control method during your BIODAZOLE treatment and within the first month of discontinuation of the drug.
Immediately consult your doctor if you notice that you are pregnant during your treatment.

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Breast-feeding
Ask your doctor or pharmacist for advice before taking this medicine.
It is not known whether BIODAZOLE is excreted in human breast milk or not. However as with many drugs may excrete in human breast milk, nursing mothers should be cautious.

Driving and using machines:
No effect on the ability to drive or use machines has been reported.

Important information about some of the ingredients of BIODAZOLE
This medicine contains lactose. If you are told by your doctor before that you have intolerance for some sugars, consult your doctor before taking this medicinal product.
This medical product contains sodium more than 1 mmol (23 mg) in each tablet. If you are on a controlled sodium diet, please tell your doctor.

Taking with other medicines
It may be unfavorable to take BIODAZOLE with the following drugs:
- Cimetidine
- Dexamethasone
- Praziquantel
- Theophylline

There may be other drugs which may interact with BIODAZOLE. Do not start taking a new medicinal product including, but not limited with vitamins, minerals and herbal products before informing your doctor.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to take BIODAZOLE
Always use your tablets as recommended by your doctor. General dosage regime is as follows:
Instructions for appropriate use and dosage / administration frequency:
Cyst Hydatid Disease:
In individuals with a body weight of 60 kg or more than 60 kg;
400 mg is taken twice daily with food for 28 days. Then discontinue for 14 days.
This dosage scheme is repeated in 3 cycles.
In individuals with a body weight less than 60 kg;
15 mg/kg is taken twice daily with food for 28 days. Then discontinue for 14 days.
This dosage scheme is repeated in 3 cycles.
Neurocysticercosis:
In individuals with a body weight of 60 kg or more than 60 kg;
400 mg is taken twice daily with food for 8-30 days.
In individuals with a body weight less than 60 kg;
15 mg/kg is taken twice daily with food for 8-30 days.
Other Helminthiasis Infections:
Dose scheme for adults:
Ascariasis, Enterobiasis (Oxyuriasis), Hookworm disease (*N. Americanus, A. Duodenale*), Trichuriasis, Trichostrongyliasis: 400 mg albendazole (1 tablet of BIODAZOLE 400 mg Film Tablet) is taken as a single dose. Treatment may be repeated after 3 weeks.
Taeniasis (*T.sainata, T.solium)* and Strongyloidiasis: 400 mg albendazole (1 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken once daily for 3 days consecutively. Treatment may be repeated after 3 weeks.
Capillariasis: 200 mg albendazole (1/2 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken twice daily for 10 days.
Trichinosis: 400 mg albendazole (1 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken twice daily for 15 days.
Chlonorchiasis: 400 mg albendazole (1 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken once or twice daily for 7 days and 10 mg/kg albendazole is taken twice daily for 7 days.
Giardiasis: 400 mg albendazole (1 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken once daily for 3 days.
Method and route of administration:
BIODAZOLE is for oral use only.
Take tablets on a full stomach with at least a glass of water (approximately 120 ml).

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Some persons, especially children, may have difficulty in swallowing the tablets as a whole. In such a case, tablets should be swallowed with water after crushing or chewing.
Different Age Groups:
Use in Children:
There are limited data on children under 6 years of age.
In Neurocysticercosis and cyst hydatic disease, dosage scheme recommended for adults is applied.
In treatment of Ascariasis, Enterobiasis (Oxyuriasis), hookworm disease (*N.americanus, A.duodenale*) Trichuriasis:
- In children up to 2 years of age: 200 mg albendazole (1/2 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken once as a single dose. Dose may be repeated after 3 weeks.
- In children over 2 years of age: The recommended dose scheme for adults is applied.

In Treatment of Taeniasis and Strongygloidiasis:
- In children up to 2 years of age: 200 mg albendazole (1/2 tablet of BIODAZOLE 400 mg Film Coated Tablet) is taken once as a single dose for 3 days consecutively. Treatment may be repeated after 3 weeks.
- In children over 2 years of age: The recommended dose scheme for adults is applied.

In treatment of capillariasis: Twice daily dose of 200 mg (1/2 tablet of BIODAZOLE 400 mg Film Coated Tablet).
In treatment of Trichostrongyliasis: A single dose of 400 mg albendazole (1 tablets of BIODAZOLE 400 mg Film Coated Tablet).
Use in Elderly:
The same dose as that applied in adults may be used.
Special Conditions:
Renal Impairment:
If you have renal impairment, inform your doctor with regards to dose adjustment.
Hepatic Impairment:
If you have hepatic impairment, inform your doctor with regards to dose adjustment.

Please ask your doctor or pharmacist if you think that the effect of BIODAZOLE is too strong or too weak.

If you take more BIODAZOLE than you should:
If you take more BIODAZOLE than you were told to, contact your doctor or pharmacist.
A supportive and symptomatic treatment is applied.

If you forget to take BIODAZOLE:
If you have forgotten to take the drug, do not worry; you can take it as soon as you remember. If the dosing time for the upcoming dose is very close, wait until then and resume your normal dosing schedule.
Do not take a double dose to make up for a forgotten dose.

Possible effects of discontinuation of BIODAZOLE treatment:
Take your medicinal product during the entire time recommended by your doctor. Your symptoms may disappear during treatment, do not discontinue the treatment in such a case.

4. Possible side effects
Like all medicines, BIODAZOLE can also cause side effects in patients with hypersensitivity to any of its ingredients.

Stop taking BIODAZOLE if you experience conditions given below and inform your doctor or apply to the emergency department of the nearest hospital IMMEDIATELY:
- Hives (a generally itchy skin condition)
- Difficulty in breathing
- Swelling of the face, lips, tongue and throat

All these are very serious side effects. If you have one of these side effects, it means that you have serious allergy to BIODAZOLE. You may need immediate medical attention and to be hospitalized. All of the above-listed very serious side effects are rarely seen.

If you notice any of the following side effects, tell your doctor immediately, or contact the emergency department at your nearest hospital:
- Easy bruising and bleeding, unusual weakness
- Fever, sore throat, severe headache, peeling and red skin rash
- Fever accompanied by chills, body aches and flu symptoms

All these are serious side effects. Immediate medical attention may be necessary. These serious side effects are rarely encountered.

If you experience any of the following side effects, tell your doctor:
- Stomachache
- Nausea, vomiting
- Headache, dizziness
- Temporary hair loss

These are mild side effects of BIODAZOLE. Frequency of these side effects is not known and can not be estimated with the available data.

Reporting of side effects
Please talk to your doctor, pharmacist or nurse in case you experience a side effect which is included or not included in this patient information leaflet. Also, please report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM), via clicking "Drug Side Effect Report" icon on www.titck.gov.tr or via calling the side effect report line on 0 800 314 00 08. By reporting the experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.

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

5. How to store BIODAZOLE
Store BIODAZOLE by keeping out of the reach and sight of children in its original package.
Store at room temperature below 25°C.

Use in line with the expiry date.
Do not use BIODAZOLE after the expiry date which is stated on the packaging.
Do not use BIODAZOLE if you notice any failure/defect in the product and/or packaging.

This patient information leaflet is approved on 04.08.2014.