PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Eskazole

Tablets

Each tablet contains albendazole 400 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 - "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Eskazole is a medicine with antiprotozoal and antihelmintic activity against tissue and intestinal parasites, especially indicated for the treatment of a hydatid cyst.

Eskazole is indicated for the treatment of the following systemic helminth diseases: echinococcosis or hydatid disease.

Eskazole is indicated for the treatment of hydatid cysts caused by *Echinococcus granulosus* and *Echinococcus multilocularis* in hydatid disease.

Eskazole may be used as first-line therapy in patients where surgical intervention is not feasible because of anatomic location or the presence of multiple cysts.

Eskazole is indicated for the treatment of liver, lung and peritoneal cysts.

Eskazole may be used as a co-adjunct to surgical treatment, both before and after surgery.

Therapeutic group: An antihelmintic medicine, derivatives of benzimidazole.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to albendazole or to any of the additional ingredients contained in this medicine (listed in section 6).
- you are pregnant or think you may be pregnant. Women of childbearing potential are advised to use effective contraception method during treatment and for one month after completing it.

Special warnings regarding use of the medicine

Talk to your physician before taking Eskazole.

- Your physician will perform liver function tests before starting each treatment cycle and at least every 2 weeks during the cycle. If the enzymes are significantly increased, treatment should be discontinued. Your physician will assess whether you can continue treatment with Eskazole once liver enzymes have returned to normal.

- Your physician will perform blood counts at the start of treatment and every two weeks during treatment to monitor your blood counts. Treatment with albendazole should be discontinued if clinically significant decreases in blood cell counts occur.

- If you are a woman of childbearing age: In order to avoid administering Eskazole during the first months of pregnancy, treatment should only be initiated following a negative result in a pregnancy test. This test should be repeated at least once before initiating the next treatment cycle. You should avoid pregnancy for at least one month after treatment discontinuation.

- Before starting treatment with Eskazole, in rare cases of neurocysticercosis in the retina, your physician will check for retinal lesions. If these lesions are

observed, the benefit of the therapy will be weighed against the possibility of retinal damage.

- If you are being treated for a parasitic infection, you may also have a rare and serious brain infection called neurocysticercosis and you may not know it. When the parasites are killed a reaction occurs in the brain. Symptoms include seizures, headache and vision problems.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

It has been reported that cimetidine (used to treat stomach ulcers), praziquantel (used to treat parasitic infections) and dexamethasone (used to treat inflammation and allergy) increase the plasma levels of the albendazole active metabolite.

It has been reported that ritonavir (used to treat HIV infections), phenytoin, carbamazepine or phenobarbital (used to treat fits [seizures] and epilepsy) may reduce the plasma levels of the albendazole active metabolite.

Pregnancy and breast-feeding

Eskazole should not be used if you are pregnant or think you may be pregnant. Women of childbearing age are advised to take effective contraceptive measures during treatment and for one month after completing it.

Treatment should only be started after a negative pregnancy test result.

There is insufficient information regarding the excretion of albendazole in breast milk. Therefore, Eskazole should not be used when breast-feeding.

Driving and using machines

Eskazole can cause dizziness. Therefore, caution is advised when driving or using machines.

Important information about some of the ingredients in the medicine

Eskazole contains lactose

If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicine.

Eskazole contains benzyl alcohol

This medicine contains 0.98 mg of benzyl alcohol in each tablet.

Benzyl alcohol can cause allergic reactions.

Ask your physician or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build up in your body and cause side effects (metabolic acidosis).

Ask your physician or pharmacist for advice if you have liver or kidney disease. This is because large amounts of benzyl alcohol can accumulate in the body and cause adverse effects (metabolic acidosis).

Benzyl alcohol has been linked to the risk of adverse effects including breathing problems ("gasping syndrome") in young children.

Eskazole contains E110 colorant (pigment)

This medicine may cause allergic reactions since it contains colorant (pigment) E110 (Color FD&C Yellow #6 Aluminum Lake 20-24% FDA).

It can cause asthma, especially in patients allergic to aspirin.

Eskazole contains sodium

This medicine contains less than 1 millimole (23 mg) sodium per tablet and is therefore considered “sodium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician’s instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Do not exceed the recommended dose.

Dosages are dependent on the parasites involved, the weight of the patient, and the severity of the infection.
Eskazole should be taken with food. Swallow the tablets with water. For those people who experience difficulties in swallowing the tablets whole, particularly young children, the tablets may be crushed or chewed with a little water. It is permissible to crush/halve/chew.

Use in children and adolescents
Eskazole is not intended for children under 6 years of age.

Use in elderly
Experience in patients aged 65 and over is limited. Reports indicate that no dose adjustment is required; however, albendazole should be used with caution in elderly patients with evidence of hepatic dysfunction.

Use in patients with renal impairment
No dose adjustment is required; however, patients with evidence of renal impairment should be carefully monitored.

Use in patients with hepatic impairment
Patients with abnormal liver function test results (transaminases) prior to starting treatment with albendazole should be carefully evaluated and treatment should be discontinued if hepatic enzymes significantly increase or if blood counts decrease to a clinically significant level.

If you accidentally have taken a higher dosage
There is no experience of overdose with Eskazole.

If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

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

If you stop taking the medicine

Adhere to the treatment regimen recommended by your physician.

Even if your health condition improves, do not stop treatment with the medicine without consulting the physician. Follow your physician's instructions carefully to ensure that your treatment results are not compromised.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Eskazole may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

The following grading is used to categorize the frequency of side effects:

Very common side effect (occurring in at least 1 in 10 patients)

Common side effect (occurring in at least 1 in 100 patients)

Uncommon side effect (occurring in at least 1 in 1,000 patients)

Rare side effect (occurring in at least 1 in 10,000 patients)

Very rare side effect (occurring in fewer than 1 in 10,000 patients)

Use in systemic helminth infections:

Blood and lymphatic system disorders

Uncommon side effect: leukopenia

Very rare side effects: pancytopenia, aplastic anemia, agranulocytosis

An association has been found between leukopenia and albendazole when treating patients with echinococcosis.

Patients with hepatic disease, including hepatic echinococcosis, appear to be more sensitive to bone marrow suppression.

Immune system disorders

Uncommon side effects: hypersensitivity reactions including rash, pruritus and urticaria

Nervous system disorders

Very common side effect: headache

Common side effect: dizziness

Gastrointestinal disorders

Common side effects: gastrointestinal disturbances (abdominal pain, nausea and vomiting)

An association has been found between gastrointestinal disturbances and albendazole when treating patients with echinococcosis.

Hepatobiliary disorders

Very common side effect: mild to moderate elevation of hepatic enzymes

Uncommon side effect: hepatitis

Skin and subcutaneous tissue disorders

Common side effect: reversible alopecia (thinning of hair, and moderate hair loss)

Very rare side effects: erythema multiforme, Stevens-Johnson syndrome

General disorders

Common side effect: fever

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health

homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Microcrystalline cellulose (E460), maize starch, lactose, croscarmellose sodium, povidone, orange flavor, vanilla flavor (contains benzyl alcohol and propylene glycol (E-1520)), magnesium stearate, sodium lauryl sulfate, passion fruit flavor, sodium saccharin, Colour FD&C Yellow #6 Aluminum Lake 20-24% FDA (E110).

- What the medicine looks like and the contents of the package:
  Eskazole tablets are mottled, pale orange, oval, biconvex, with a score line on one side and embossed with "ALB 400" on the other. The tablets have a characteristic fruity odor.
  Eskazole is available in a pack containing 60 tablets or in blisters of 12, 56 and 100 tablets.
  Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

- Manufacturer: GlaxoSmithKline Consumer Healthcare South Africa (PTY) Limited, Cape Town, South Africa.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-55-27464

Revised in November 2024.

Esk PT v9D