

**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 side effects such as dizziness and the symptoms may mean that you are not fit to drive (see section 4). Do not drive or use machines unless you are sure that you are not affected.

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 ("gaspings 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

- If there are more than 6 hours until the next dose, take it as soon as you remember, and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten doses.

If you are not sure what to do, consult your physician or pharmacist.

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.

Serious skin reactions: consult your physician immediately

A small number of people who take Eskazole experience allergic reactions that are potentially life-threatening and may give rise to more severe problems if untreated.

The symptoms of these reactions include:

- Skin rash, which may form blisters and appear as small bull's eyes (central dark spots surrounded by a lighter area, with a dark ring around the edge) [*erythema multiforme*].

- A disseminated skin rash with blisters and peeling of the skin occurring especially around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).

If you experience any of these symptoms, contact a physician immediately.

Symptoms that you should bear in mind

Seizures (*fits*) and other symptoms

People who are being treated for parasitic infections may also have a serious and rare condition called *neurocysticercosis*, which means the presence of parasites in the brain. Treatment with Eskazole triggers a reaction in the brain when the parasites are eliminated. Watch out for the following combination of symptoms:

- headache which may be severe
- feeling sick (*nausea*) and vomiting
- seizures (*fits*)
- vision problems

If you experience any of these symptoms, **contact a physician immediately.**

Very common side effects

These may affect **more than 1 in every 10** people:

- headache.

Very common side effects that may appear in your blood tests:

- increase in liver enzymes.

Common side effects

These may affect **up to 1 in every 10** people:

- dizziness
- stomach pain
- feeling sick (*nausea*)

- vomiting
- fever
- thinning of the hair and moderate hair loss (*alopecia*), which is reversible

Uncommon side effects

These may affect **up to 1 in every 100** people:

- allergic reaction including skin rash and itching
- inflammation of the liver (*hepatitis*).

Uncommon side effects that may appear in your blood tests:

- reduction in the number of white blood cells (*leukopenia*).

Very rare side effects

These may affect up to **1 in every 10,000** people:

Severe skin rash

- Skin rash, which may include blisters and appear as small bull's eyes, central dark spots surrounded by a lighter area, with a dark ring around the edge (*erythema multiforme*).
- A disseminated skin rash with blisters and peeling of the skin occurring especially around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).

If you experience any of these symptoms, contact a physician immediately (see 'serious skin reactions' at the start of section 4).

Very rare side effects that may appear in your blood tests:

- reduction in the number of all blood cells (*pancytopenia*).
- severe reduction in the number of white blood cells (*agranulocytosis*).
- bone marrow suppression leading to an insufficient quantity of blood cells (*aplastic anaemia*).

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, maize starch, lactose, croscarmellose sodium, povidone, orange flavour, vanilla flavour (contains benzyl alcohol and propylene glycol (E-1520)), magnesium stearate, sodium lauryl sulfate, passion fruit flavour, 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

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