PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with
a physician's prescription only

Eskazole

Each tablet contains albendazole 400 mg.
A list of the additional ingredients is detailed in section 6.

Read this 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 the active ingredient, or to any of the additional ingredients contained in the medicine (as detailed in section 6).
- You are pregnant or think you may be pregnant. Women of child-bearing age are advised to take effective contraceptive measures during treatment and within one month of termination of treatment.

Before treatment with Eskazole, tell the physician if:
- You have abnormal liver function test results prior to initiating treatment. This should be carefully monitored due to the hepatotoxic potential of albendazole.
- You are a woman of child-bearing age: In order to avoid administering Eskazole during the first months of pregnancy, treatment should only be initiated following a negative 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.

Special warnings regarding use of the medicine
- A transient elevation of liver enzymes is observed during treatment: Generally, the level of liver enzymes returns to the normal level on discontinuation of treatment. However, cases of hepatitis have been reported. Therefore, it is recommended to perform liver function tests before the start of each treatment cycle and at least every two weeks during treatment. If enzymes are found to have increased significantly (by more than twice the normal upper limit), treatment should be discontinued. Treatment with Eskazole may be restarted when liver enzymes have returned to within normal limits, but patients should be carefully monitored for recurrence.
- Bone marrow suppression is observed following treatment: Blood counts should be performed at the start of treatment and every two weeks during the treatment. Albendazole should be discontinued if clinically significant decreases in blood cell counts occur.
- In rare cases of retinal neurocysticercosis, the patient should be examined for retinal lesions before beginning treatment with Eskazole. If these lesions are observed, the benefit of the therapy should be weighed against the possibility of retinal damage.
- You may also have a rare and serious infection called neurocysticercosis and you may not know it. When the parasites are killed a reaction occurs in the brain. Symptoms include fits (seizures), headache and vision problems.

Eskazole and other medicines
If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.
It has been reported that cimetidine (used to treat stomach ulcers), praziquantel (used to treat parasitic infections) and dexamethazone (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 [convulsions] and epilepsy) may reduce the plasma levels of the albendazole active metabolite.

The use of Eskazole with food and drink
Eskazole should be taken with food.

Pregnancy, breast-feeding and fertility
Eskazole should not be used if you are pregnant or think you may be pregnant. Women of child-bearing age are advised to take effective contraceptive measures during treatment and within one month of termination of treatment.
There are no available data about the use of the medicine when breast-feeding in humans or animals. Therefore, Eskazole should not be used when breast-feeding.

Driving and operating machinery
Eskazole could cause dizziness. Therefore, caution is advised when driving or operating machinery.

Important information about some of the ingredients of Eskazole
This medicine contains lactose
If you have been told by your physician that you have an intolerance to some sugars, refer to your physician before taking this medicine.
This medicine contains sunset yellow lake E110 colorant
This medicine may cause allergic reactions since it contains sunset yellow lake E110 colorant.
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 this preparation according to the physician's instructions. Check with your physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
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 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
Eskazole is not recommended 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 are significantly increased or if blood counts decrease to a clinically significant level.

If you accidentally take too high a dose
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 forget to take Eskazole
Do not take a double dose to make up for the forgotten doses.
Adhere to the treatment regimen as recommended by the physician.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician.
Do not take medicines in the dark! Check the label and the dose each time you take the 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 the list of side effects. You may not experience 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.
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 SHOULD THE MEDICINE BE STORED?

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.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains -
Microcrystalline cellulose E460, maize starch, lactose, croscarmellose sodium, povidone, orange flavor, vanilla flavor, magnesium stearate, sodium lauryl sulfate, passion fruit flavor, sodium saccharin, sunset yellow lake E110.

What the medicine looks like and the contents of the package -
Eskazole is available in a pack containing 60 tablets and in blisters of 12, 56 and 100 tablets.
Not all pack 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.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in May 2017, and updated in May 2018, in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-55-27464