

ESKAZOLE

albendazole

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some of the common questions about ESKAZOLE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking ESKAZOLE against the expected benefits.

If you have any concerns about taking this medicine talk to your doctor or pharmacist.

Keep this leaflet with this medicine. You may need to read it again.

What is ESKAZOLE used for?

ESKAZOLE contains albendazole as the active ingredient.

ESKAZOLE is used to clear worms or parasites from the gut and other tissues. ESKAZOLE is effective in a number of different conditions caused by parasites including hydatid disease and neurocysticercosis.

ESKAZOLE is thought to kill these parasites by causing them to starve. The eggs, larvae and adult parasites are affected.

Your doctor may have prescribed ESKAZOLE for another reason. Ask your doctor if you have any questions about why ESKAZOLE has been prescribed for you.

There is no evidence that ESKAZOLE is addictive.

Before you take ESKAZOLE

Do not take if:

- you have had an allergic reaction to albendazole or any of the other ingredients contained in this medicine. Albendazole is also contained in ZENTEL. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.
- if you have taken albendazole before and became unwell, tell your doctor or pharmacist before taking the first dose.
- you are allergic to medicines similar to albendazole such as mebendazole (Sqworm or Vermox) or thiabendazole (Mintezol).
- **YOU KNOW OR SUSPECT YOU ARE PREGNANT.** Pregnancy must be avoided (ie use effective contraceptive measures) during treatment, and for one month after stopping ESKAZOLE.
- **you are breast feeding.** Your baby can absorb albendazole from breast milk if you are breast feeding. Breast feeding should be stopped while taking ESKAZOLE, and for at least 1 month after finishing treatment.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

ESKAZOLE should not be given to children unless instructed by a doctor.

ESKAZOLE can:

- reduce the number of blood cells produced in the body.
- increase the levels of enzymes (chemicals found in the blood) that are produced by the liver.

Your doctor may arrange to take blood samples to check the number of blood cells and your liver enzymes before and during treatment. Depending on the results you may have to stop or interrupt your treatment.

There is only a small amount of information available about the use of ESKAZOLE in children. Use in children under 6 years of age is not recommended.

Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.

Before you start taking ESKAZOLE tell your doctor if:

- you are or think you may be pregnant or if you intend to become pregnant. Pregnancy must be avoided (ie use effective contraceptive measures) during treatment, and for one month after stopping ESKAZOLE.
- you are breast feeding. Breast feeding should be stopped while taking ESKAZOLE, and for at least 1 month after finishing treatment.
- you have any liver problems.

Look out for important symptoms:

Fits (seizures) and other symptoms:

People being treated for parasite infections can also have a rare and serious brain infection called neurocysticercosis but they don't always know that they have it. A reaction happens in the brain when the parasites are killed. The symptoms include fits (seizures), headache and problems with your vision.

Taking other medicines with ESKAZOLE:

The effects of some medicines may be affected if other medicines are used at the same time. You should therefore tell your doctor if you use other medicines regularly, have used other medicines until recently or wish to use other medicines at the same time as ESKAZOLE. This includes those medicines that you buy without a prescription. Your doctor will be able to tell you if any problems could occur when taking ESKAZOLE with other medicines.

How do I take it

Follow your doctors' instructions about how and when to use ESKAZOLE. Read the direction label carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

How much to take:

Your doctor will advise how many doses are needed each day, and for how long you will need to take ESKAZOLE. The usual daily dose for adults is one ESKAZOLE tablet taken twice daily with meals.

The dose in children aged 6 years and over depends on their body-weight.

When to take:

Take ESKAZOLE in the morning with breakfast and at night with the evening meal.

Take ESKAZOLE at the same time each day.

Taking your medicine at the same time each day will give the best effect. It will also help you to remember when to take your medicine.

If you forget to take:

Take the missed tablets as soon as you remember. Then take the next dose at the time it is normally due. Do not take two doses within an hour of each other.

Do not try to make up for missed doses by taking more than one dose at a time.

Taking more than the prescribed dose can increase the chance of unwanted side effects.

How to take:

ESKAZOLE should be taken with a meal.

Swallow the tablets with water. For people, particularly young children, who may find it difficult to swallow the tablets whole, they can be crushed or chewed with a little water.

How long to take:

Keep taking ESKAZOLE for as long as your doctor tells you. Do not stop taking ESKAZOLE just because you feel better. ESKAZOLE is usually taken for a 28 day course. You may need to take more than one course. Usually you will need to wait for fourteen days before starting a second, or third course of tablets.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (13 11 26) or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of ESKAZOLE. Do this even if there are no signs of discomfort or poisoning.

While you are taking it

Things you must do:

Take ESKAZOLE exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking ESKAZOLE.

Tell your doctor or pharmacist you are taking ESKAZOLE, before starting any other medicines.

Some medicines may affect the way other medicines work.

Things to be careful of:

Be careful driving or operating machinery until you know how you react to ESKAZOLE.

ESKAZOLE may cause dizziness in some people.

Side effects

Besides their main effect, medicines may have some unwanted effects. Unwanted effects do not always occur in every person.

Fits (seizures) and other symptoms:

People being treated for parasite infections may also have a rare and serious condition called neurocysticercosis meaning that they have parasites in the brain. By taking ESKAZOLE a reaction happens in the brain when the parasites are killed.

Look for the following combination of symptoms:

- Headache, which can be severe
- Nausea and vomiting
- Fits (seizures)
- Problems with your vision.

Contact a doctor immediately if you get these.

Most unwanted effects following ESKAZOLE are mild, and may disappear without stopping ESKAZOLE. However, some side effects may need medical treatment. Tell the doctor about any effect which is troublesome or ongoing.

Mild effects:

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- headache or dizziness
- vomiting or feeling sick or stomach pains
- mild skin rash
- thinning of the hair or some hair loss. This has been reported rarely. However, hair growth returns to normal after the tablets are stopped.

More serious effects:

Tell your doctor immediately if you notice any of the following:

- unusual bleeding or bruising
- yellowing of the skin and eyes also called jaundice
- fever

Stop taking ESKAZOLE and contact a doctor immediately or go to the emergency department of your nearest hospital if any of the following happens:

- swelling of limbs, face, mouth or throat
- shortness of breath or breathing difficulties
- hives or severe skin reactions

These are signs of a severe allergic reaction to ESKAZOLE. Allergy to ESKAZOLE is rare.

If you are receiving ESKAZOLE for neurocysticercosis you may

experience a worsening of your symptoms (such as headache and high temperature) when you first start to take ESKAZOLE.

Other rare events that have been reported with ESKAZOLE include:

- inflammation of the pancreas
- severe liver effects
- effects on the eyes
- blood disorders
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome).

You should tell the doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with ESKAZOLE.

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your tablets in the original pack until it is time to take them.

Keep the pack in a cool dry place. Store below 30°C

Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop taking ESKAZOLE ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like:

ESKAZOLE 400mg chewable tablets are a mottled, pale orange, rounded oblong, biconvex, tablets with a score line on one side and engraved ALB 400 on the other. ESKAZOLE tablets have a distinctive fruity odour

The tablets can be broken in half.

ESKAZOLE tablets are available in blisters packs of 56* and bottles of 60 tablets.

*Currently not marketed

Ingredients:

Active ingredient:

ESKAZOLE tablets contain 400mg of albendazole per tablet.

Inactive ingredients:

ESKAZOLE tablets also contains

lactose monohydrate

microcrystalline cellulose

maize starch

croscarmellose sodium

povidone

sodium lauryl sulfate

sunset yellow CI 15985

sodium saccharin

magnesium stearate

vanilla flavour 54286 BP 0551 (PI 1633)

passion fruit flavour 54442 AP0551 (PI 1629)

orange flavour 55588 AP 0551 (PI 1631)

ESKAZOLE tablets do not contain sucrose, gluten or tartrazine.

Sponsor

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos Street St Leonards, NSW 2065.

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