

ESKAZOLE tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ESKAZOLE?

ESKAZOLE contains the active ingredient albendazole. 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.

For more information, see Section [1. Why am I using ESKAZOLE?](#) in the full CMI.

2. What should I know before I use ESKAZOLE?

Do not use if you have ever had an allergic reaction to albendazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ESKAZOLE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ESKAZOLE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ESKAZOLE?

- The usual daily dose for adults is one tablet taken twice daily with meals. The dose for children depends on their body weight. Your doctor will advise you.
- Swallow ESKAZOLE tablets with water. The tablets can also be crushed or chewed with a little water.
- Your doctor will advise how many doses are needed each day, and for how long you will need to take ESKAZOLE.
- Follow your doctors' instructions about how and when to use ESKAZOLE.

More instructions can be found in Section [4. How do I use ESKAZOLE?](#) in the full CMI.

5. What should I know while using ESKAZOLE?

Things you should do	<ul style="list-style-type: none">• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly. ESKAZOLE is usually taken for a 28 day course.• Do not give this medicine to anyone else.
Driving or using machines	<ul style="list-style-type: none">• ESKAZOLE may cause dizziness in some people.• Be careful driving or operating machinery until you know you react to ESKAZOLE.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C• Keep the pack in a cool dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using ESKAZOLE?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ESKAZOLE tablets

Active ingredient: *albendazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ESKAZOLE.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ESKAZOLE.

Where to find information in this leaflet:

- [1. Why am I using ESKAZOLE?](#)
- [2. What should I know before I use ESKAZOLE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ESKAZOLE?](#)
- [5. What should I know while using ESKAZOLE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ESKAZOLE

ESKAZOLE contains the active ingredient albendazole.

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.

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

Your doctor may have prescribed ESKAZOLE for another reason.

There is no evidence that ESKAZOLE is addictive.

2. What should I know before I use ESKAZOLE?

Warnings

Do not use ESKAZOLE if:

- you are allergic to albendazole, or any of the ingredients listed at the end of this leaflet. Albendazole is also contained in ZENTEL. Signs of an allergic reaction may include an itchy skin rash, shortness of breath and swelling of the face or tongue.
- 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 (Emverm or Vermox) or thiabendazole (Mintezol).
- you know or suspect you are pregnant.
Pregnancy must be avoided (i.e. use effective contraceptive measures) during treatment, and for one month after stopping ESKAZOLE.
- you are breastfeeding.
Your baby can absorb albendazole from breast milk if you are breastfeeding. Breastfeeding 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 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.

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

Check with your doctor if you have any liver problems.

Use in children

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

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

- Tell your doctor if you are or think you may be pregnant or if you intended to become pregnant.**
Pregnancy must be avoided (i.e. use effective contraceptive measures) during treatment, and for one month after stopping ESKAZOLE.
- Tell your doctor if you are breastfeeding or intend to breastfeed.**
Breastfeeding should be stopped while taking ESKAZOLE, and for at least 1 month after finishing treatment.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ESKAZOLE.

4. How do I use ESKAZOLE ?

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

- The usual daily dose for adults is one ESKAZOLE tablet taken twice daily with meals.
- Your doctor will advise how many doses are needed each day, and for how long you will need to take ESKAZOLE.
- The dose in children aged 6 years and over depends on their body-weight.

When to take ESKAZOLE

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.

How to take ESKAZOLE

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 ESKAZOLE

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.

If you forget to take ESKAZOLE

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.

If you use too much ESKAZOLE

If you think that you have used too much ESKAZOLE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ESKAZOLE?

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ESKAZOLE affects you.

ESKAZOLE may cause dizziness in some people.

Looking after your medicine

Keep your tablets in the original pack where the temperature stays below 30°C.

Keep the pack in a cool dry place away from moisture, heat or sunlight.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any 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 side effects with ESKAZOLE are mild and may disappear without stopping ESKAZOLE. However, some side effects may need medical treatment.

Tell your doctor about any effect which is troublesome or ongoing.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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.	Speak to your doctor if you have any of these less serious side effects and they worry you.

More serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• unusual bleeding or bruising• yellowing of the skin and eyes also called jaundice• fever.	Tell your doctor immediately if you notice any of these serious side effects.
<ul style="list-style-type: none">• swelling of limbs, face, mouth or throat• shortness of breath or breathing difficulties• hives or severe skin reactions.	Stop taking ESKAZOLE and contact a doctor straight immediately or

go straight to the Emergency Department at your nearest hospital if any of these symptoms occur.

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).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ESKAZOLE contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• albendazole 400 mg/tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• microcrystalline cellulose• maize starch• croscarmellose sodium• povidone• sodium lauryl sulfate

	<ul style="list-style-type: none"> • sunset yellow FCF aluminium lake • saccharin sodium • magnesium stearate • sonaflo vanilla 080911 • sonaflo passionfruit 171011 • Orange Flavour 501071 AP 0551.
Potential allergens	<ul style="list-style-type: none"> • sugars as lactose. • saccharin.

ESKAZOLE tablets do not contain sucrose, gluten or tartrazine.

Do not take this medicine if you are allergic to any of these ingredients.

What ESKAZOLE looks like

ESKAZOLE 400 mg chewable tablets are a mottled pale orange rounded oblong biconvex tablets with a score line on one side and embossed "ALB 400" on the other side, with a characteristic fruity odour. Available in bottles of 60 tablets.

The tablets can be broken in half.

Australian Registration number: AUST R 97505.

Who distributes ESKAZOLE

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards, NSW 2065
Australia

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