

ZENTEL tablets

albendazole

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about ZENTEL. 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 ZENTEL 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 ZENTEL IS USED FOR

ZENTEL contains albendazole as the active ingredient.

ZENTEL is used to clear worms or parasites from the gut and other tissues. ZENTEL is effective against threadworm or pinworm, roundworm, whipworm, tapeworm and hookworm among others.

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

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

There is no evidence that ZENTEL is addictive.

BEFORE TAKING IT

Do not take ZENTEL if:

- you have had an allergic reaction to albendazole or any of the other ingredients contained in this medicine. Albendazole is also contained in Eskazole. 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, 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 ZENTEL. In order to avoid taking ZENTEL during early pregnancy, treatment with ZENTEL should only be started during the first week of having your period or after a negative pregnancy test.
- **you are breast feeding.** Your baby can absorb albendazole from breast milk if you are breast feeding. Breast feeding should be stopped while taking ZENTEL, and for at least 5 days after finishing treatment.

- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

ZENTEL is not recommended for children under 2 years of age.

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

Before you start taking ZENTEL 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 ZENTEL. In order to avoid taking ZENTEL during early pregnancy, treatment with ZENTEL should only be started during the first week of having your period or after a negative pregnancy test.
- you are breast feeding. Breast feeding should be stopped while taking ZENTEL, and for at least 5 days after finishing treatment.
- you have any liver problems.

Taking other medicines with ZENTEL:

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 ZENTEL. 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 ZENTEL with other medicines.

HOW TO TAKE IT

Follow your doctors' instructions about how and when to use ZENTEL. 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 ZENTEL. The usual dose for adults and children older than 2 years of age, is two ZENTEL tablets as a single dose.

For other conditions the dose prescribed by your doctor may be different. You should take the full course of tablets, and not just stop when you feel better.

Your doctor may need to see you two to four weeks after taking the dose or course. This is to make sure that ZENTEL has worked. A second dose or course of ZENTEL is sometimes needed.

How to take

You will be told whether to take the tablets with food or on an empty stomach, and it is important you follow these instructions. ZENTEL tablets are usually taken on an empty stomach. In some conditions the tablets may need to be taken after food.

ZENTEL tablets may be taken crushed or chewed or swallowed whole. No special laxative or fasting is needed.

If you forget to take

Take the missed tablets as soon as you remember. If you have been prescribed more than a single dose,

do not try to make up for missed doses by taking more than two tablets at a time.

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

OVERDOSE

Immediately telephone your doctor or Poisons Information Centre (In Australia telephone 131126. In New Zealand telephone 0800 POISON) or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of ZENTEL. Do this even if there are no signs of discomfort or poisoning. Be sure to show the doctor the ZENTEL packet. There are unlikely to be any serious problems following an overdose of ZENTEL.

WHILE YOU ARE TAKING IT

Things you must do:

Take ZENTEL exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking ZENTEL.

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

Some medicines may affect the way other medicines work.

You may require monitoring of your liver function or white blood cell counts. Patients with liver disease may be monitored more closely.

If you are having a blood test done, tell your doctor you are taking ZENTEL.

Keep any follow up appointments with your doctor. It may be necessary to check that ZENTEL has worked. A second dose or course of ZENTEL is sometimes needed.

Things to be careful of:

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

ZENTEL 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.

Most unwanted effects following ZENTEL are mild, and may disappear without stopping ZENTEL. 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, stomach pains or diarrhoea
- mild skin rash or itchiness

More Serious Effects

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

- fever
- bone pain
- headache
- tiredness, shortness of breath, looking pale.
- frequent infections
- unusual bleeding or bruising.
- yellowing of the skin and eyes, also called jaundice, dark coloured urine and/or light coloured stools.
- infections of the throat, mouth, skin or nasal passage.
- Seizures
- Blurred or abnormal vision
- Unusual behaviour

- Unusual numbness or weakness
- Unusual taste, smell or hearing

Stop taking ZENTEL 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 ZENTEL. Allergy to ZENTEL is rare.

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 ZENTEL.

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 ZENTEL ask your pharmacist what to do with any tablets that are left over.

PRODUCT DESCRIPTION

What it looks like

ZENTEL is available as a white to off-white, circular, biconvex, bevel edged film coated tablet, with a pentagonal pyramid on each face containing 200mg of albendazole.

ZENTEL tablets do not contain sucrose, gluten or tartrazine.

ZENTEL tablets are available in blisters* or bottles of 6, 60 and 100 tablets. *Currently not marketed (Not all pack sizes may be marketed).

Ingredients

Active ingredient:

Each tablet contains 200mg of the active ingredient albendazole

Inactive ingredients:

lactose monohydrate
maize starch
microcrystalline cellulose
magnesium stearate
sodium lauryl sulphate
povidone
hypromellose, macrogols
propylene glycol
sodium starch glycollate
saccharin sodium

SPONSOR

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

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