# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 ZENTEL?

ZENTEL contains the active ingredient albendazole. It is used to clear worms or parasites from the gut and other tissues.

For more information, see Section 1. Why am I using ZENTEL? in the full CMI.

# 2. What should I know before I use ZENTEL?

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 ZENTEL? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with ZENTEL 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 ZENTEL?

- Your doctor will tell you how many ZENTEL tablets to take and for how long. The usual dose for adults and children over 2 years old is two tablets as a single dose. This may vary depending on the condition.
- ZENTEL tablets are usually taken on an empty stomach. However, your doctor may tell you to take it after food depending on the condition.
- ZENTEL tablets may be taken crushed, chewed or swallowed whole.
- Your doctor may need to see you two to four weeks after taking the dose or course to make sure that it has worked. Sometimes, a second dose or course of ZENTEL is needed.

More instructions can be found in Section <u>4. How do I use ZENTEL?</u> in the full CMI.

# 5. What should I know while using ZENTEL?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using ZENTEL.</li> <li>Take ZENTEL exactly as your doctor has prescribed.</li> </ul>
Things you should not do	<ul> <li>Do not change the dose of ZENTEL without first checking with your doctor.</li> <li>Do not use ZENTEL to treat any other complaints unless your doctor says to.</li> </ul>
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ZENTEL affects you.
Looking after your medicine	<ul> <li>Keep ZENTEL tablets in the pack until it is time to take them.</li> <li>Keep it in a cool dry place, away from moisture or heat where the temperature stays below 30°C.</li> </ul>

For more information, see Section 5. What should I know while using ZENTEL? in the full CMI.

# 6. Are there any side effects?

Mild side effects of ZENTEL include headache or dizziness, vomiting or feeling sick, stomach pains or diarrhoea and mild skin rash or itchiness.

Serious side effects of ZENTEL include fever, bone pain, headache, tiredness, shortness of breath, and looking pale, frequent infections, unusual bleeding or bruising, yellowing of the skin and eyes (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 and an allergic reaction.

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.

# **ZENTEL chewable tablets**

Active ingredient: albendazole

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using ZENTEL.

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 ZENTEL.

### Where to find information in this leaflet:

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

# 1. Why am I using ZENTEL?

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.

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

Your doctor may have prescribed ZENTEL for another reason.

# 2. What should I know before I use ZENTEL?

### Warnings

### Do not use ZENTEL if:

 you are allergic to albendazole, similar medicines (such as mebendazole), or any of the ingredients listed at the end of this leaflet.
 Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of

Always check the ingredients to make sure you can use this medicine. Check with your doctor or pharmacist if you are unsure.

the expiry date printed on the label has passed.

the body; rash, itching or hives on the skin.

the packaging is torn or shows signs of tampering.

#### Check with your doctor if you:

- have any other medical conditions, especially the following:
  - liver problems
- take any medicines for any other condition.
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- have taken albendazole before and became unwell.

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 <u>6. Are there any side effects?</u>

### Pregnancy and breastfeeding

ZENTEL must not be used if you are or suspect you are pregnant. Pregnancy must be avoided (i.e. by using 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.

Tell your doctor if you are or think that you may be pregnant, or you are planning to become pregnant.

#### ZENTEL should not be used if you are breastfeeding.

Your baby can absorb albendazole from breast milk if you are breastfeeding. Breastfeeding should be stopped while taking ZENTEL, and for at least 5 days after treatment.

### Use in children

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

# 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.

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

The following drugs may increase the levels of ZENTEL in the body, and may increase the risk of side effects:

- cimetidine
- praziquantel
- dexamethasone.

The following drugs may reduce the levels of ZENTEL in the body, which may reduce its effectiveness.

- ritonavir
- phenytoin
- carbamazepine

• phenobarbital.

This list is not exhaustive.

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

# 4. How do I use ZENTEL?

#### How much to take

- Your doctor will advise how many ZENTEL tablets to take and for how long. The usual dose for adults and children older than 2 years of age is two 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.

## When to take ZENTEL

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

### How to take it

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

# If you forget to take it

#### 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.

### If you take too much

If you of anyone else has taken a large amount of ZENTEL,

#### 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 ZENTEL?

#### Things you should do

Take ZENTEL exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking ZENTEL.

Remind any doctor, dentist, or pharmacist you visit that you are taking ZENTEL, especially 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 you should not do

Do not change the dose of ZENTEL without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use ZENTEL to treat any other complaints unless your doctor says to.

#### Driving or using machines

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

ZENTEL may cause dizziness in some people.

### Looking after your medicine

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

Store it 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.

Heat and dampness can destroy some medicines.

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?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

# Less serious side effects

Less serious side effects	What to do
<ul> <li>fever</li> <li>headache or dizziness</li> <li>vomiting or feeling sick, stomach pains or diarrhoea</li> <li>mild skin rash or itchiness.</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they are troublesome or ongoing

# Serious side effects

Serious side effects	What to do
<ul> <li>bone pain</li> <li>tiredness, shortness of breath, looking pale</li> <li>frequent infections</li> <li>thinning of hair, moderate hair loss</li> <li>unusual bleeding or bruising</li> <li>yellowing of the skin and eyes, also called jaundice, dark coloured urine and/or light coloured stools</li> <li>infections of the throat, mouth, skin or nasal passage</li> <li>seizures</li> <li>blurred or abnormal vision</li> <li>unusual behaviour</li> <li>unusual numbness or weakness</li> <li>unusual taste, smell or hearing.</li> </ul>	Tell your doctor immediately if you experience any of these serious side effects.
<ul> <li>Signs of allergic reaction</li> <li>swelling of limbs, face, mouth or throat</li> <li>shortness of breath or breathing difficulties</li> <li>hives or severe skin reactions.</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

# 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 <u>www.tga.gov.au/reporting-problems</u>. 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 ZENTEL contains

Active ingredient	<ul> <li>albendazole 200 mg/tablet</li> </ul>
(main ingredient)	
Other ingredients	<ul> <li>lactose monohydrate</li> </ul>
(inactive ingredients)	<ul> <li>maize starch</li> </ul>
	<ul> <li>microcrystalline cellulose</li> </ul>
	<ul> <li>magnesium stearate</li> </ul>
	<ul> <li>sodium lauryl sulphate</li> </ul>
	<ul> <li>povidone</li> </ul>
	<ul> <li>hypromellose</li> </ul>
	<ul> <li>propylene glycol</li> </ul>
	<ul> <li>sodium starch glycollate</li> </ul>
	<ul> <li>saccharin sodium.</li> </ul>
Potential allergens	<ul> <li>sugars as lactose</li> </ul>
	• saccharin sodium.

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

# What ZENTEL looks like

ZENTEL is a white to off-white, round, biconvex, bevel edged film coated chewable tablet, marked with 'Z' on one side and plain on the other side. Available in bottles of 6 tablets.

Australian registration number: AUST R 50815

### Who distributes **ZENTEL**

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

This leaflet was revised in January 2025.