

# ZENTEL™

## Albendazole

**Read all of this leaflet carefully before you start taking this medicine.**

### WHAT IS IN THIS MEDICINE

Tablet containing 200 mg or 400 mg albendazole.  
4 % w/v suspension to be taken orally; 4 g albendazole per 100 ml.

### WHAT ZENTEL IS AND WHAT IT IS USED FOR

**ZENTEL** is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against the intestinal and tissue worm infections.

**ZENTEL** is used for the treatment of common worm infections of the gut, such as the following conditions caused by sensitive intestinal helminths/protozoa:

- Pinworm infection (enterobiasis)
- Hookworm disease (ancylostomiasis and necatoriasis)
- Dwarf tapeworm infection (hymenolepsiasis)
- Pork/beef tapeworm infections (taeniasis)
- Threadworm infection (strongyloidiasis)
- Roundworm infection (ascariasis)
- Whipworm infection (trichuriasis)
- Liver fluke infections (clonorchiasis and opisthorchiasis)
- Hookworm (animal origin) causing skin disease (cutaneous larva migrans)
- Giardia infection (giardiasis in children)

### HOW TO TAKE ZENTEL

The recommended dose of **ZENTEL** is as follows:

Adults and children over 2 years of age 400 mg as a single dose.

Children 1-2 years of age 200 mg as a single dose.

**ZENTEL** should not to be used in children aged under 1 year.

No special procedures, such as fasting or purging, are required.

If the patient is still symptomatic after a single course of treatment, they must consult a Healthcare Professional for further treatment.

The maximum duration of treatment will vary according to your condition. Please refer to the table below for information on maximum doses for each condition. Do not exceed the maximum daily doses and treatment durations recommended.

Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water; alternatively the tablets may be crushed. The suspension can also be administered as an alternative.

<b>Indications</b>	<b>Age</b>	<b>Dose</b>	<b>Period</b>	<b>Maximum Dose Recommended</b>
Pinworm infection * Hookworm disease Roundworm infection Whipworm infection	adults and children over 2 years of age  children 1-2 years of age	400 mg [two 200 mg tablet(s) or 10 ml 4% suspension]#  200 mg (one 200 mg tablet or 5 ml 4% suspension)	single dose (to be taken on an empty stomach)  single dose (to be taken on an empty stomach)	Single dose, 400 mg  Single dose, 200 mg
Threadworm infection Pork/beef tapeworm infection Dwarf tapeworm infection **	adults and children over 2 years of age	400 mg (#see above)	one dose per day for 3 days (to be taken on an empty stomach)	400 mg per day (1200 mg for 3 consecutive days)
Liver fluke infections ***	adults and children over 2 years of age	400 mg (#see above)	two doses per day for 3 days (to be taken with food)	800 mg per day (2400 mg over a 3 day period)
Cutaneous larva migrans	adults and children over 2 years of age	400 mg	Once daily for 1 to 3 days (to be taken with food)	400 mg per day (Up to 1200 mg over a 3 day period)
Giardia infection	children 2 - 12 years of age only	400 mg (#see above)	one dose per day for 5 days (to be taken on an empty stomach)	400 mg per day (2000 mg over a 5 day period)

\*In order to obtain a complete cure in the case of pin-worm infestation, measures should be taken to maintain strict hygiene. Relatives and individuals sharing the same housing should also take a course of treatment.

\*\* In cases of proven dwarf tapeworm infection (Hymenolepiasis), a repeat course of the medicine in 10-21 days is recommended.

\*\*\*Advice should be sought from your Healthcare Professional 1 month after treatment to confirm fluke eradication.

- Elderly

Elderly patients with hepatic impairment (liver problems) must seek advice from a Healthcare Professional before taking this medicine.

- Renal Impairment (Kidney problems)

If you have been diagnosed with renal impairment (kidney problems), seek advice from a Healthcare Professional before taking this medicine.

- Hepatic Impairment (Liver problems)

If you have been diagnosed with hepatic impairment (liver problems), seek advice from a Healthcare Professional before taking this medicine.

## **DON'T TAKE ZENTEL**

If you are pregnant, if you think you could be pregnant, or if you are planning to become pregnant (see PREGNANCY AND BREAST FEEDING).

If you are allergic (hypersensitive) to **ZENTEL** or any other ingredients of **ZENTEL** (see section on WHAT ZENTEL CONTAINS).

## **WHAT YOU NEED TO KNOW BEFORE TAKING ZENTEL**

In order to avoid administering **ZENTEL** during early pregnancy, women of childbearing age should initiate treatment within the first week of menstruation or after a negative pregnancy test.

If you develop severe headache, nausea and vomiting, fits and/or problems with your vision after taking this medicine, consult a Healthcare Professional immediately.

**ZENTEL** may cause liver problems. Please consult a Healthcare Professional if you experience yellowing of the skin or eyes, dark coloured urine and/or light coloured stools. Patients diagnosed with hepatic or renal impairment (liver or kidney problems) must seek advice from a Healthcare Professional before taking this medicine.

Keep out of the sight and reach of children.

## **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/HCP if you use other medicines regularly, have used other medicines 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.

## **PREGNANCY AND BREAST FEEDING**

**ZENTEL** should not be administered during pregnancy or in women thought to be pregnant (see WHAT YOU NEED TO KNOW BEFORE TAKING **ZENTEL**).

Patients who are breast feeding must seek advice from a Healthcare Professional prior to taking this medicine.

## **DRIVING AND USING MACHINES**

When driving vehicles or operating machinery it should be taken into account that dizziness has been reported after using **ZENTEL** (see Side Effects).

## **SIDE EFFECTS**

Uncommon side effects (up to 1 in 100 people) are headache, dizziness, stomach pain, nausea, vomiting and diarrhoea.

Rare side effects (up to 1 in 1000 people) are hypersensitivity reactions including rash, pruritus and urticaria, and changes in liver blood test. Please consult a Healthcare Professional if you experience yellowing of the skin or eyes, dark coloured urine and/or light coloured stools.

Very rare side effects (up to 1 in 10,000 people) are serious blistering skin rashes with swelling and peeling (erythema multiforme, Stevens-Johnsons syndrome). Please contact a Healthcare Professional if you notice any of these symptoms.

## **OVERDOSE**

Please consult a Healthcare Professional for advice in the event of overdose.

## **HOW TO STORE ZENTEL**

Do not use **ZENTEL** after the expiry date shown on the pack.

Tablets: Store below 30°C.

Suspensions: Store below 30°C and protect from direct sunlight.

## **INSTRUCTIONS FOR USE/HANDLING**

Suspensions: Shake well before use.

## **WHAT ZENTEL CONTAINS**

### ZENTEL Tablet 200mg

Lactose  
Maize starch  
Polyvidone  
Sodium lauryl sulphate  
Sodium starch glycollate  
Microcrystalline cellulose  
Sodium saccharin  
Magnesium stearate  
Purified water

### **Film coating**

Methylhydroxypropyl cellulose 15  
Methylhydroxylpropyl 5  
Propylene glycol  
Purified water

### ZENTEL Tablet 400mg

Lactose  
Microcrystalline cellulose  
Maize starch  
Croscarmellose sodium  
Povidone  
Sodium lauryl sulphate  
Sunset yellow lake  
Sodium saccharin  
Magnesium stearate  
Orange flavour

Vanilla favour  
Passion fruit flavour

ZENTEL Suspension 400mg/10ml

Sodium Lauryl Sulfate  
Glycerin  
Methylparaben  
Propylparaben  
Sodium Carboxymethylcellulose 7MF  
Sodium Carboxymethylcellulose 7HF  
Saccharin sodium  
Orange flavour  
Vanilla favour  
Passion fruit flavour

**VERSION NUMBER: cGDS v1.0 (SI)**

**DATE OF ISSUE: 15 May 2014**

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