

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 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.

Indications	Age	Dose	Period	Maximum Dose Recommended
Pinworm infection*	adults and children over 2 years of age	400 mg [two 200 mg tablet(s) or 10 ml 4% suspension]#	single dose (to be taken on an empty stomach)	Single dose, 400 mg
Hookworm disease				
Roundworm infection	children 1-2 years of age	200 mg (one 200 mg tablet or 5 ml 4% suspension)	single dose (to be taken on an empty stomach)	Single dose, 200 mg
Whipworm infection				
Threadworm 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)
Pork/beef tapeworm infection				
Dwarf tapeworm infection**				
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
Colour FD&C Yellow #6 Aluminium Lake 20-24% FDA
Sodium saccharin
Magnesium stearate
Orange flavour
Vanilla flavour

Passion fruit flavour

ZENTEL Suspension 400mg/10ml

Sodium Lauryl Sulfate

Glycerin

Methylparaben

Propylparaben

Sodium Carboxymethylcellulose 7MF

Sodium Carboxymethylcellulose 7HF

Saccharin sodium

Orange flavour

Vanilla flavour

Passion fruit flavour

Not all presentations may be available locally.

VERSION NUMBER: cGDS v2.0 (SI)

DATE OF ISSUE: 16 March 2018

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