
ZENTEL

Versión GDSv28-IPIv01

ZENTEL

Albendazole

Qualitative and Quantitative Composition

Tablets:

Each tablet contains 400 mg of albendazole.

Oral Suspensions:

4 % w/v oral suspension 400 mg albendazole per 10 mL.

2 % w/v oral suspension 400 mg albendazole per 20 mL.

Clinical Information

Indications

ZENTEL is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against the following intestinal and tissue parasites:

INTESTINAL INFECTIONS AND CUTANEOUS LARVA MIGRANS

Short duration treatment at low dose.

ZENTEL is indicated in the treatment of the following clinical conditions caused by sensitive intestinal helminths/protozoa (see *Pharmacodynamics*)

- enterobiasis (pinworm infection)
- ancylostomiasis and necatoriasis (hookworm disease)
- hymenolepsiasis (dwarf tapeworm infection)
- taeniasis (pork/beef tapeworm infection)
- strongyloidiasis (threadworm infection)
- ascariasis (roundworm infection)
- trichuriasis (whipworm infection)
- clonorchiasis and opisthorchiasis (*Opisthorchis viverrini* and/or *Clonorchis sinensis* infections) (liver fluke infections)
- cutaneous larva migrans [hookworm (animal origin) causing skin disease]
- giardiasis in children (*Giardia* infection)

Dosage and Administration

Pharmaceutical Form:

Tablet.

Oral suspension.

Dosage

Indications	Age	Dose	Period	Maximum daily dose and maximum dose for the whole treatment
- Ascariasis (roundworm infection) - Enterobiasis (pinworm infection) - Ancylostomiasis and necatoriasis (hookworm disease) - Trichuriasis (whipworm infection)	Adults and children over 2 years of age.	400 mg [one 400 mg tablet(s) or 10 mL 4% or 20 mL 2% suspension]#	Single dose.	400 mg, single dose
- Ancylostomiasis and necatoriasis (hookworm disease) - Trichuriasis (whipworm infection)	Children 1 to 2 years of age.	200 mg (5 mL 4% or 10 mL 2% suspension)	Single dose.	200 mg, single dose
- Suspected or confirmed strongyloidiasis (threadworm infection) - Taeniasis (pork/beef tapeworm infection) - Hymenolepsiasis† (dwarf tapeworm infection)	Adults and children over 2 years of age.	400 mg (#see above)	One dose per day for 3 consecutive days. †In cases of proven hymenolepsiasis, retreatment in 10 to 21 days is recommended.	400 mg per day [1200 mg for the whole treatment (over 3 consecutive days)]
- Clonorchiasis - Opisthorchiasis (liver fluke infections)	Adults and children over 2 years of age.	400 mg (#see above)	One dose twice daily for 3 days.	800 mg per day [2400 mg for the whole treatment (over 3 consecutive days)]
- Cutaneous larva migrans [hookworm (animal origin) causing skin disease]	Adults and children over 2 years of age.	400 mg	One dose per day for 1 to 3 days.	400 mg per day [Up to 1200 mg for the whole treatment (over 3 consecutive days)]
- Giardiasis	Children 2 to 12 years of age only.	400 mg (#see above)	One dose per day for 5 days.	400 mg per day

Indications	Age	Dose	Period	Maximum daily dose and maximum dose for the whole treatment
				[2000 mg for the whole treatment (over 5 consecutive days)]

Method of Administration

If individual is still symptomatic after a single course of treatment, they must consult a healthcare professional.

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

The maximum duration of treatment will vary according to the indication.

Maximum daily doses and treatment durations should not be exceeded.

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

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

Special Patient Populations

Elderly

There are limited data on the use of ZENTEL in patients 65 years of age and over. However, there is no evidence that clearance of these compounds would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Individuals with renal impairment must consult a healthcare professional before taking ZENTEL.

Renal Impairment

Since renal elimination of albendazole and its primary metabolite, albendazole sulfoxide, is negligible, it is unlikely that clearance of these compounds would be altered in these patients. No dosage adjustment is required. Individuals with renal impairment must consult a healthcare professional before taking ZENTEL.

Hepatic Impairment

Since albendazole is rapidly metabolised by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, hepatic impairment would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Individuals with hepatic impairment must consult a healthcare professional before taking ZENTEL.

Contraindications

- ZENTEL should not be administered during pregnancy or in women thought to be pregnant.
- ZENTEL is contraindicated in patients with a known history of hypersensitivity to albendazole or other constituents of the dose forms.

Warnings and Precautions

Pregnancy

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

Pre-Existing Neurocysticercosis

Treatment with ZENTEL may uncover pre-existing neurocysticercosis, particularly in areas with high taeniasis (tapeworm) infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment. Individuals experiencing such symptoms must consult a doctor as soon as possible.

Influence on Hepatic Enzymes

ZENTEL treatment has been associated with mild to moderate elevations of hepatic enzymes. Hepatic enzymes generally normalise on discontinuation of treatment. Individuals with hepatic impairment must seek medical advice before starting the treatment (see *Dosage and Administration and Adverse Reactions*).

Renal Impairment

Individuals with renal impairment must seek medical advice before starting the treatment. (see *Dosage and Administration and Adverse Reactions*).

Excipients

ZENTEL tablets contain sunset yellow FCF (E110 or FD&C Yellow No 6) which may cause allergic-type reactions.

ZENTEL tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take ZENTEL tablets.

ZENTEL tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

ZENTEL suspension contains benzoic acid which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). ZENTEL suspension contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Interactions

Clinically relevant interactions are not anticipated at the dose and duration of treatment for non-prescription use.

Pregnancy and Lactation

Fertility

There are no data on the effects of ZENTEL on human fertility.

No effects on male fertility have been observed in animal studies at clinically relevant exposures (see *Non-Clinical Information*).

Pregnancy

ZENTEL should not be administered during pregnancy or in women thought to be pregnant (see *Contraindications*).

Lactation

ZENTEL should not be used during lactation unless the potential benefits outweigh the potential risks associated with the treatment. Patients who are breast feeding must seek medical advice before starting the treatment.

Effects on Ability to Drive and Use Machines

There have been no studies to investigate the effect of *ZENTEL* on driving performance or the ability to operate machinery. However, when driving vehicles or operating machinery, it should be taken into account that dizziness may be expected after using *ZENTEL* (see *Adverse Reactions*).

Adverse Reactions

Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (>1/10), common (>1/100 and <1/10), uncommon (>1/1000 and <1/100), rare (>1/10 000 and <1/1000) and very rare (<1/10 000), including isolated reports.

Immune System Disorders

Rare: Hypersensitivity reactions including rash, pruritus and urticaria

Nervous System Disorders

Uncommon: Headache and dizziness

Gastrointestinal Disorders

Uncommon: Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea.

Hepatobiliary Disorders

Rare: Elevations of hepatic enzymes

Skin and Subcutaneous Tissue Disorders

Very rare: Erythema multiforme, Stevens-Johnson syndrome

Overdose

Symptoms and signs

No data are available with regard to overdosage of *ZENTEL*.

Treatment

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

Pharmacological Properties

Pharmacodynamics

ATC Code

P02CA03

Mechanism of Action

Albendazole is a benzimidazole carbamate with antiprotozoal and anthelmintic effects against intestinal and tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermifugal activity, and it is thought to exert its anthelmintic effect by inhibiting tubulin polymerisation. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

Pharmacodynamic Effects

Albendazole is active against intestinal parasites, including:

Nematodes

- Ascaris lumbricoides (roundworm)
- Trichuris trichiura (whipworm)
- Enterobius vermicularis (pinworm/threadworm)
- Ancylostoma duodenale (hookworm)
- Necator americanus (hookworm)
- Strongyloides stercoralis
- Hookworms that cause cutaneous larva migrans.

Cestodes

- Hymenolepis nana (dwarf tapeworm)
- Taenia solium (pork tapeworm)
- Taenia saginata (beef tapeworm)

Trematodes

- Opisthorchis viverrini and Clonorchis sinensis

Protozoa

- Giardia lamblia (intestinalis or duodenalis)

Pharmacokinetics

Absorption

In humans, albendazole is poorly absorbed (less than 5%) following oral administration.

Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulfoxide, has been reported to achieve peak plasma concentrations from 1.6 to 6.0 micromol/L when taken with breakfast.

Metabolism

Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma.

Elimination

The plasma half-life of albendazole sulfoxide is 8.5 hours.

Special Patient Populations

Elderly

No specific studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics.

Renal Impairment

The pharmacokinetics of albendazole in patients with impaired renal function have not been studied.

Hepatic Impairment

The pharmacokinetics of albendazole in patients with impaired hepatic function have not been studied.

Clinical studies

No data available.

Non-Clinical Information

Although albendazole treatment-related effects were observed in rat testes, no effects on litter size were observed in a male fertility study. Albendazole has been shown to be teratogenic and embryotoxic in rats and rabbits. Albendazole was negative for evidence of mutagenicity or genotoxicity in a panel of *in vitro* (including Ames inactivated and activated) and *in vivo* tests. In long-term toxicity studies conducted in rats and mice at daily doses of up to 30 times the recommended human doses, no treatment-related tumour formation was seen.

Pharmaceutical Information

List of Excipients

Tablets 400 mg:

Lactose (see *Warnings and Precautions*)

Microcrystalline cellulose

Maize starch

Croscarmellose sodium

Povidone K30

Sodium lauryl sulphate

Sunset yellow FCF (E110 or FD&C Yellow No 6) (see *Warnings and Precautions*)

Sodium saccharin

Magnesium stearate

Flavourings

Suspension (2%, 4%):

Aluminium magnesium silicate

Carboxymethylcellulose sodium

Glycerin

Polysorbate 80

Sorbitan monolaureate

Potassium sorbate

Benzoic acid (see *Warnings and Precautions*)

Sorbic acid

Silicone antifoam 1510

Saccharin sodium

Flavourings

Shelf Life

The expiry date is indicated on the packaging.

Storage

The storage conditions are detailed on the packaging.

Nature and Contents of Container

Tablets: Blister packs, polypropylene containers and cap.

Oral suspensions: Glass/Plastic bottle with polypropylene or aluminium cap.

Incompatibilities

There are no special requirements for use on handling of this product.

Use and Handling

Oral suspensions: Shake well before use.

Not all presentations are available in every country.

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