# ZENTEL

# Albendazole

**Non-prescription for treatment of**

**INTESTINAL INFECTIONS AND CUTANEOUS LARVA MIGRANS**

**Formulation and Strength**

Tablets: 400 mg.

Suspension: 400 mg/20 ml.

## CLINICAL INFORMATION

**Indication(s)**

Albendazole is a benzimidazole carbamate with antihelmintic and antiprotozoal activity against intestinal and tissue parasites.

Albendazole is indicated in the treatment of the following clinical 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)

### Dosage and Administration

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 the indication. Please refer to the table below for information on maximum doses for each indication. Do not exceed the maximum daily doses and treatment durations recommended.

Not to be used in children aged under 1-year.

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 tablets may be crushed. The suspension can also be administered as an alternative.

| **Infection** | **Age** | **Usual Dose** | **Duration of dose** | **Maximum Dose Recommended** |
|---|---|---|---|---|
| **Pinworm/infection**<br>**Hookworm disease**<br>**Roundworm infection**<br>**Whipworm infection** | adults and children over 2 years of age | 400 mg | single dose | single dose, 400mg |
| | children 1 to 2 years of age | 200 mg | single dose | single dose,<br>200mg |
| Suspected or confirmed **Threadworm infection**<br>**Dwarf Tapeworm† Pork/beef Tapeworm infections** | adults and children over 2 years of age | 400 mg | Once daily for 3 consecutive days<br>†In cases of proven dwarf tapeworm retreatment in 10 to 21 days is recommended. | 400mg per day (1200mg for 3 consecutive days) |
| **Liver fluke** | adults and children over 2 years of age | 400 mg | Twice daily for 3 days | 800mg per day (2400mg 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 | 400mg per day (Up to 1200mg over a 3 day period) |
| **Giardia infection** | children 2 to 12 years of age only | 400 mg | Once daily for 5 days | 400mg per day (2000mg over a 5 day period |

## Populations

- Elderly

Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required; however, elderly patients with evidence of hepatic dysfunction must seek advice from a Healthcare Professional before taking this medicine (*see Hepatic Impairment and Phar Pharmacokinetics*).

- 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; however, patients who have been diagnosed with renal impairment must seek advice from Healthcare Professional before taking this medicine (see *Pharmacokinetics*).

- Hepatic Impairment

Since albendazole is rapidly metabolized 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. Patients who have been diagnosed with hepatic impairment must seek advice from a Healthcare Professional before taking this medicine (see *Pharmacokinetics*).

## Contraindications

Albendazole must not be used during pregnancy.

Albendazole is contraindicated in patients with a known history of hypersensitivity to albendazole or other constituents of the dose forms.

## Warnings and Precautions

In order to avoid administering albendazole during early pregnancy, women of childbearing age should initiate treatment within the first 10 days of starting their menstrual period or immediately after a negative pregnancy test.

Treatment with albendazole may uncover pre-existing neurocysticercosis, particularly in areas with high rates of tapeworm (taeniasis) 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. Patients experiencing such symptoms, after taking this medicine, must seek advice from a Healthcare Professional as soon as possible.

Albendazole treatment has been associated with mild to moderate elevations of hepatic enzymes. Hepatic enzymes generally normalise on discontinuation of treatment. Patients diagnosed with hepatic impairment must seek advice from a Healthcare Professional before taking this medicine *(see Dosage and Administration: hepatic impairment and Adverse Reactions).*

Patients diagnosed with renal impairment must seek advice from a Healthcare Professional before taking this medicine *(see Dosage and Administration: renal impairment and Adverse Reactions).*

Keep out of the sight and reach of children.

Albendazole suspension contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane.

## Interactions

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

## Pregnancy and Lactation

### Fertility

No text

### Pregnancy

Albendazole must not be used during pregnancy (see Contraindications).

### Lactation

Adequate human and animal data on use during lactation are not available. Thus albendazole should not be used during breast feeding unless the potential benefits are considered to outweigh the potential risks associated with treatment. Patients who are breast feeding must seek advice from a Healthcare Professional prior to taking this medicine.

## Ability to perform tasks that require judgement, motor or cognitive skills

Adverse effects on the ability to drive or operate machinery have not been observed.

## Adverse Reactions

The following convention is used for classification of adverse reaction frequencies:

| | |
|---|---|
| Very common | ≥1/10 |
| Common | ≥1/100 and <1/10 |
| Uncommon | ≥ 1/1000 and < 1/100 |
| Rare | ≥ 1/10,000 and < 1/1000 |
| Very rare | < 1/10,000 |

**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

## Overdosage

Symptoms and Signs (optional)

*No Text*

Treatment

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

Clinical Pharmacology

Pharmacodynamics

ATC Code

P02CA03 QP52AC11

*Mechanism of Action*

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

Pharmacokinetics

*Absorption*

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

*Distribution*

Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulphoxide, has been reported to achieve plasma concentrations of 0.698 μg/mL 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 sulphoxide is 8 ½ h.

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 has not been studied.

### Hepatic Impairment

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

### Clinical Studies

*No Text*

## NON-CLINICAL INFORMATION

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

### Excipients

As registered locally.

### Shelf-Life

***Tablets:***

Shelf life is indicated on the packaging.

***Suspensions:***

Shelf life is indicated on the packaging.

### Storage

***Suspensions:***

Protect from direct sunlight.

*Nature and Content of Container*

***Tablets:***

Blister packs.

Polypropylene containers and cap.

***Suspensions:***

Glass/plastic bottle with aluminium cap.

## Incompatibilities

Not relevant.

## Use and Handling

Shake well before use.

***GSK is committed to the effective collection and management of human safety information relating to our products and we encourage healthcare professionals to report adverse events to us on* +254 20 693 3200 or email us** ke.safety@gsk.com

Full Prescribing Information is available on request from GlaxoSmithKline Pharmaceutical Kenya Limited, P.O. Box 78392-00507, 23 Likoni Road, Nairobi, Kenya.

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