GLOBAL DATASHEET

Albendazole

Non-prescription for treatment of

INTESTINAL INFECTIONS AND CUTANEOUS LARVA MIGRANS

GLOBAL TECHNICAL INFORMATION

TITLE

Albendazole.

SCOPE

Trade Name[s]*

The Trade names for this product include:

INTESTINAL INFECTIONS AND CUTANEOUS LARVA MIGRANS **(Short duration treatment at low dose)**
ZENTEL
ALBEN
NEMATIL
AZENTEL

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Formulation and Strength

Tablets: 200 mg, 400 mg.

Suspension: 400 mg/20 ml, 400 mg/10 ml.

Excipients

It is mandatory for country product information to include both the complete list of excipients for all locally marketed presentations, and any locally imposed excipient warning statements.

Tablets 200 mg (wet granulation only)	**Tablets 400 mg (wet granulation only)**	**Tablets 400 mg (roller-compaction)**	**Suspension**
Lactose	Lactose monohydrate	Lactose	Aluminium magnesium silicate
Maize starch	Maize starch	Microcrystalline cellulose	Carboxymethylcellulose sodium
Polyvidone	Povidone	Maize starch	Glycerin
Sodium lauryl sulphate	Sodium lauryl sulphate	Croscarmellose sodium	Polysorbate 80
Sodium starch glycollate	Sodium starch glycollate	Povidone K30	Sorbitan monolaureate
Microcrystalline cellulose	Microcrystalline cellulose	Sodium lauryl sulphate	Potassium sorbate
Sodium saccharin	Sunset yellow lake	Sunset yellow lake	Benzoic acid (see Warnings and Precautions)
Magnesium stearate	Sodium saccharin	Sodium saccharin	Sorbic acid
	Magnesium stearate	Magnesium stearate	Silicone antifoam 1510
	Flavourings	Flavourings	Saccharin sodium
			Flavourings
Film coating	**Film coating**		
Methylhydroxypropylcellulose 15	Methylhydroxypropylcellulose 15		
Methylhydroxypropylcellulose 5	Methylhydroxypropylcellulose 5		
Propylene glycol.	Propylene glycol.		

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 **Hookworm disease** **Roundworm infection** **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, 200mg
Suspected or confirmed **Threadworm infection** **Dwarf Tapeworm† Pork/beef Tapeworm infections**	adults and children over 2 years of age	400 mg	Once daily for 3 consecutive days †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 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

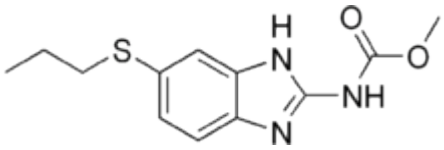
No Text

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

Chemical Structure



Shelf-Life

Tablets:

5 years at 25°C

Suspensions:

2% Suspension (400 mg/20 ml)
4 years at 25°C
3 years at 30°C

4% Suspension (400 mg/10 ml)

3 years at 25°C

2 years at 30°C

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.

GLOBAL CONSUMER INFORMATION

Section and Line reference in GTI	Consumer information
Indications, lines 23-38	For treatment of common worm infections of the gut (pinworm, roundworm, hookworm and whipworm). This medicine may also be used to treat other types of worm infections but only after medical advice.
Dosage and Administration, lines, 39-54	Adults and children over 2-years of age 400mg as a single dose. Children 1-2 years of age 200mg as a single dose. Do not exceed maximum single daily recommended dose for adults and children over 2-years (of 400mg) or children 1-2-years (200mg). If you still experience symptoms after taking a single dose, please seek medical advice for further treatment. Some people, particularly young children, may experience problems swallowing the tablets whole. Tablets can be split, chewed with a little water or crushed.
Contraindications, lines, 74-77	Do not use if you are pregnant. Do not use if you are allergic to albendazole or any other ingredients.
Warnings & Precautions, lines, 78-81	Women of childbearing age should begin treatment during the first 10 days of starting their period, or immediately after a negative pregnancy test, in order to avoid taking this medicine during early pregnancy.
Warnings & Precautions, lines, 82-88	If you develop severe headache, nausea and vomiting, fits and/or problems with your vision after taking this medicine, consult a Healthcare Professional immediately.
Warnings &	This medicine may cause liver problems. Please consult a

Precautions, lines, 89-96	Healthcare Professional if you experience yellowing of the skin or eyes. If you have been diagnosed with liver or kidney problems, seek advice from a Healthcare Professional before taking this medicine.
Warnings & Precautions, line, 97	Keep out of the sight and reach of children.
Warnings & Precautions [Suspension only], lines, 98-99	Avoid contact with the skin, eyes, mouth or nose, as albendazole suspension may cause irritation.
Lactation, lines, 108-113	If you are breast feeding, please seek advice from a Healthcare Professional before using this medicine.
Adverse reactions, lines, 116-138	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 changes in liver blood test. Please consult a Healthcare Professional if you experience yellowing of the skin or eyes. Very rare side effects (up to 1 in 10, 000 people) are serious blistering skin rashes with swelling and peeling. Please contact a Healthcare Professional if you notice any of these symptoms.
Overdose, lines, 139-144	Please consult a Healthcare Professional for advice in the event of overdose.