Summary of Product Characteristics

ZENTEL™

Albendazole

QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablet containing either 200 mg or 400 mg albendazole.
4 % w/v suspension to be taken orally; 4 g albendazole per 100 ml.
2 % w/v suspension to be taken orally; 2 g albendazole per 100 ml.

PHARMACEUTICAL FORM

Tablet
Suspension

CLINICAL PARTICULARS

Indications

ZENTEL is a benzimidazole carbamate with antihelmintic and antiprotozoal activity against the following intestinal and tissue parasites: Round-worm (Ascaris lumbricoides), pin-worm (Enterobius vermicularis), hook-worm (Necator americanus, Ancylostoma duodenale), whip-worm (Trichuris trichiura), thread-worm (Strongyloides stercoralis), tape-worm (Taenia spp and Hymenolepis nana only in the case of associated parasitism), Chlonorchiasis (Chlonorchis sinensis), Opisthorchiasis (Opisthorchis viverrini) and cutaneous larva migrans; Giardiasis (G.lamblia, G.duodenalis, G.intestinalis, Lamblia intestinalis) in children.

Dosage and Administration

Dosage

Indications	Age	Dose	Period
- Round-worm - Pin-worm* - Hook-worms - Whip-worm	adults and children over 2 years of age	400 mg [two 200 mg or one 400 mg tablet(s) or 10 ml 4% or 20 ml 2% suspension]#	single dose
	children 1-2 years of age	200 mg (one 200 mg tablet or 5 ml 4% or 10 ml 2% suspension)	single dose
- Strongyloidiasis	adults and children over 2 years of age	400 mg (#see above)	one dose per day for 3 days

- Taeniasis - Hymenolepiasis[=]			
-.Chlonorchiasis - Opisthorchiasis	adults and children over 2 years of age	400 mg (#see above)	two doses per day for 3 days
- Giardiasis	children 2 - 12 years of age only	400 mg (#see above)	one dose per day for 5 days

[*]In order to obtain a complete cure in the case of pin-worm infestation, prescribe strict measures of hygiene, also treat the relatives and individuals sharing the same housing.

[=]In cases of proven Hymenolepiasis, retreatment in 10-21 days is recommended.

Method of Administration

If the patient is not cured after three weeks, a second course of treatment is indicated.

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

The tablets can be chewed or taken with water. 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.

Special Patient Populations

Elderly

Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required, however, albendazole should be used with caution in elderly patients with evidence of hepatic dysfunction (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 with evidence of renal impairment should be carefully monitored.

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 with abnormal liver function test results (transaminases) prior to commencing albendazole therapy should be carefully monitored.

Summary of Product Characteristics

Contraindications

ZENTEL should not be administered during pregnancy, or in women thought to be pregnant.

ZENTEL is contra-indicated in patients with a known history of hypersensitivity to the drug (albendazole or constituents)

Warnings and Precautions

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.

Treatment with ZENTEL may uncover pre-existing neurocysticercosis, particularly in areas with high taenosis 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, appropriate steroid and anticonvulsant therapy should be started immediately.

ZENTEL suspension contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane. It may increase the risk of jaundice in newborn babies.

Interactions

Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

Pregnancy and Lactation

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

It is not known whether albendazole or its metabolites are secreted in human breast milk. Thus **ZENTEL** should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

Effects on Ability to Drive and Use Machines

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

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.

The following convention has been used for the classification of frequency:

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, pruritis 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

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

PHARMACOLOGICAL PROPERTIES

Pharmacokinetics

Special Patient Populations

- **Elderly**

Although no studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics, data in twenty-six hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects. The number of elderly patients treated for either hydatid disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

- **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.

PHARMACEUTICAL PARTICULARS

List of Excipients

Tablets 200 mg	**Tablets 400 mg**	**Suspension (2%, 4%)**
Lactose	Lactose	Aluminium magnesium silicate
Maize starch	Microcrystalline cellulose	Carboxymethylcellulose sodium
Polyvidone	Maize starch	Glycerin
Sodium lauryl sulphate	Croscarmellose sodium	Polysorbate 80
Sodium starch glycollate	Povidone K30	Sorbitan monolaureate
Microcrystalline cellulose	Sodium lauryl sulphate	Potassium sorbate
Sodium saccharin	Sunset yellow lake	Benzoic acid (see Warnings and Precautions)
Magnesium stearate*	Sodium saccharin	Sorbic acid
	Magnesium stearate*	Silicone antifoam 1510
	Flavourings	Saccharin sodium
Film coating		Flavourings
Methylhydroxypropylcellulose 15		
Methylhydroxypropylcellulose 5		
Propylene glycol.		

* Magnesium Stearate is of vegetable origin

Or as registered locally

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

Tablets: Store below 30°C.

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

Summary of Product Characteristics

Nature and Contents of Container

Tablets: Blister packs, polypropylene containers and cap.

Suspensions: Glass/plastic bottle with aluminium cap.

Instructions for Use/Handling

Suspensions: Shake well before use.

Not all presentations are available in every country.

Manufactured by:
GlaxoSmithKline S.A. (PTY) LTD
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Cape Town, 7460, South Africa

Marketing Authorization Holder:

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