# ZENTEL® 400 Tablets

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME AND DOSAGE FORM:**

**ZENTEL® 400** Tablets

**COMPOSITION:**

Each ZENTEL 400 tablet contains 400 mg of the active ingredient albendazole.

Excipients: lactose, microcrystalline cellulose, maize starch, croscarmellose sodium, povidone, sodium lauryl sulphate, sunset yellow lake, sodium saccharin, magnesium stearate and flavourings (orange, passion fruit and vanilla).

**PHARMACOLOGICAL CLASSIFICATION:**

A.12 Anthelmintics

**PHARMACOLOGICAL ACTION:**

**Pharmacodynamic properties**

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

Animal studies have shown that albendazole exhibits vermicidal, ovacidal and larvacidal activity and exerts its anthelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

**Pharmacokinetic properties**

In man, after oral administration, albendazole is absorbed and completely metabolised. At a dose of 6,6 mg/kg of albendazole the plasma concentration of its

main metabolite, the sulfoxide, attains a maximum of 0,25 to 0,30 µg/ml after approximately 2½ hours.

The half-life of the sulfoxide in the plasma is 8½ hours. The metabolite is essentially eliminated via the urine.

**INDICATIONS:**

ZENTEL 400 is indicated in the treatment of single or mixed intestinal parasites including *Ascaris lumbricoides* (roundworm), *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm/threadworm), *Ancylostoma duodenale* and *Necator americanus* (hookworm), *Taenia spp.* (tapeworm) and *Strongyloides stercoralis*.

ZENTEL 400 has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

**CONTRA-INDICATIONS:**

Pregnancy and lactation (see PREGNANCY AND LACTATION)

ZENTEL 400 is contra-indicated in patients with a known history of hypersensitivity to albendazole or constituents of ZENTEL 400.

**WARNINGS AND SPECIAL PRECAUTIONS:**

Leucopenia may occur when ZENTEL 400 is used for periods longer than recommended.

**In order to avoid administering ZENTEL 400 during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.**

Sub-clinical neurocystercosis may manifest after a single dose of ZENTEL 400.

Treatment with albendazole 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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Effects on ability to drive and use machines:** Since dizziness has been reported following treatment with ZENTEL 400, caution is recommended in patients performing skilled tasks.

**INTERACTIONS:**

Praziquantel increase the plasma levels of the active metabolite of ZENTEL 400.

Ritonavir, phenytoin, carbamazepine and phenobarbital may reduce plasma concentrations of the active metabolite of ZENTEL 400; albendazole sulfoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

**PREGNANCY AND LACTATION:**

ZENTEL 400 should not be administered during pregnancy or in women thought to be pregnant (refer to CONTRA-INDICATIONS).

Albendazole is known to be teratogenic and embryotoxic in animals.

Adequate human data during lactation are not available.

**DOSAGE AND DIRECTIONS FOR USE:**

**Usual Dose:**

400 mg (one ZENTEL 400 tablet) as a single dose in both adults and children over two years of age.

In heavy mixed infestation involving *Strongyloides* or *Taeniasis*, a single daily dose may be inadequate and the dose may be given for three consecutive days.

**Note:**

If the patient is not cured after three weeks, a second course of treatment may be given. No special procedures, such as fasting or purging, are required.

Albendazole has not been adequately studied in children under one year of age.

**Giardiasis (dose in children over 2 years of age):**

A single 400 mg (one ZENTEL 400 tablet) daily dose for five days.

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 and mixed with food.

**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 below).

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

**SIDE EFFECTS:**

Data from clinical studies were used to determine the frequency of very common to rare undesirable reactions.

The following convention has been used for the classification of frequency: Very common ≥ 1/10, common ≥ 1/100 to < 1/10, uncommon ≥ 1/1 000 to < 1/100, rare ≥ 1/10 000 and < 1/1 000, very rare < 1/10 000.

**Immune system disorders:**

Rare: Hypersensitivity reactions

**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:**

Rare: Rash, pruritus and urticaria.

**Post-marketing Side Effects:**

**Skin and subcutaneous tissue disorders:**

Unknown: Erythema multiforme, Stevens-Johnson syndrome.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

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

**IDENTIFICATION:**

ZENTEL 400 tablets are mottled pale orange rounded oblong biconvex tablets with a score line on one side and embossed “ALB 400” on the reverse and with a characteristic fruity odour.

**PRESENTATION:**

ZENTEL 400 tablets are available in blister pack strips of one tablet each or securitainers containing 100 or 500 tablets.

**STORAGE INSTRUCTIONS:**

Keep out of reach of children.

Store in a cool place at or below 25 °C.

**REGISTRATION NUMBER:**

30/12/0354

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1

7460

**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

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