ZENTEL™

Albendazole

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ZENTEL tablet contains 400mg albendazole.

PHARMACEUTICAL FORM

Tablet

CLINICAL PARTICULARS

Indications

ZENTEL is a benzimidazole carbamate with antihelmintic and antiprotozoal activity against intestinal and tissue parasites. ZENTEL is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown albendazole effective in the treatment of Round-worm (Ascaris lumbricoides), pin-worm/threadworm (Enterobius vermicularis), hook-worm (Necator americanus, Ancylostoma duodenale), whip-worm (Trichuris trichiura), Strongyloides stercoralis, and tape-worm (Taenia spp), ZENTEL has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

Dosage and Administration

Usual Dose:

400 mg (one ZENTEL 400 mg tablet) as a single dose in both adults and children over 2 years of age.

The tablets may be chewed, swallowed or crushed and mixed with food.

In heavy mixed infestation involving Strongyloides or Taeniasis, a single dose may be inadequate and the dose may be given for 3 consecutive days.

Note:

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

No specific 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 daily dose for five days.

The tablets may be chewed, swallowed or crushed and they should be taken with food.

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 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 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.

Interactions

Cimetidine, praziquantel and dexamethasone have been reported to increase the plasma levels of the albendazole active metabolite responsible for the systemic efficacy of the product.

Pregnancy and Lactation

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

Adequate human and animal data on use during lactation are not available.

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.

PHARMACEUTICAL PARTICULARS

List of Excipients

Lactose, Microcrystalline cellulose (Avicel pH 101), Maize starch, Croscarmellose sodium, Povidone, Sodium lauryl sulphate, Colour sunset yellow lake*, Sodium saccharin, Magnesium stearate, Vanilla flavour 54.286/BP 05.51, Passion fruit flavour 54.442/AP05.51, Orange flavour 55.588/AP05.51.

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

KEEP OUT OF THE REACH OF CHILDREN
Store in a cool place (below 25°C)

Nature and Contents of Container

ZENTEL 400 tablets are available in blister pack strips of one tablet each.

Manufactured by:
GlaxoSmithKline South Africa (Pty) Ltd
39 Hawkins Avenue
Epping Industria 1, 7460
Cape Town, South Africa

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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

GlaxoSmithKline

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