ZENTEL® GlaxoSmithKline
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 anthelmintic 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

<table>
<thead>
<tr>
<th>Indications</th>
<th>Age</th>
<th>Dose</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Round-worm</td>
<td>adults and children over 2 years of age</td>
<td>400 mg [two 200 mg or one 400 mg tablet(s) or 10 ml 4% or 20 ml 2% suspension ]#</td>
<td></td>
</tr>
<tr>
<td>- Pin-worm*</td>
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<td></td>
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<tr>
<td>- Hook-worms</td>
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<td></td>
<td></td>
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<tr>
<td>- Whip-worm</td>
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<tr>
<td>- Strongyloidias</td>
<td>adults and children over 2 years of age</td>
<td>200 mg (one 200 mg tablet or 5 ml 4% or 10 ml 2% suspension)</td>
<td>single dose</td>
</tr>
<tr>
<td>- Taeniasis</td>
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<td></td>
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<tr>
<td>- Hymenolepiasis*</td>
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</tr>
<tr>
<td>- Chlonorchiasis</td>
<td>adults and children over 2 years of age</td>
<td>400 mg (#see above)</td>
<td>two doses per day for 3 days</td>
</tr>
<tr>
<td>- Opisthorchiasis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Giardiasis</td>
<td>children 2 - 12 years of age only</td>
<td>400 mg (#see above)</td>
<td>one dose per day for 5 days</td>
</tr>
</tbody>
</table>

* 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.

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.

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.
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 in 10
common: ≥1 in 100 and <1 in 10
uncommon: ≥1 in 1,000 and <1 in 100
rare: ≥1 in 10,000 and <1 in 1,000
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
In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

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

<table>
<thead>
<tr>
<th></th>
<th>Tablets 200 mg</th>
<th>Tablets 400 mg</th>
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</thead>
<tbody>
<tr>
<td>Aluminium magnesium silicate</td>
<td>Coating:</td>
<td>Coating:</td>
</tr>
<tr>
<td>Carboxymethyl-cellulose sodium</td>
<td>Hydroxypropyl-methylcellulose 15cP</td>
<td>Hydroxypropyl-methylcellulose 15cP</td>
</tr>
<tr>
<td>Glycerin</td>
<td>Hydroxypropyl-methylcellulose 5cP</td>
<td>Hydroxypropyl-methylcellulose 5cP</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Propylene glycol</td>
<td>Propylene glycol</td>
</tr>
<tr>
<td>Sorbitan monolaurate</td>
<td>Core:</td>
<td>Core:</td>
</tr>
<tr>
<td>Potassium sorbate</td>
<td>Lactose</td>
<td>Lactose monohydrate</td>
</tr>
<tr>
<td>Benzoic acid (see Warnings and Precautions)</td>
<td>Maize Starch</td>
<td>Maize Starch</td>
</tr>
<tr>
<td>Sorbic acid</td>
<td>Polyvidone</td>
<td>Povidone</td>
</tr>
<tr>
<td>Silicone antifoam 1510</td>
<td>Sodium lauryl sulphate</td>
<td>Sodium lauryl sulphate</td>
</tr>
<tr>
<td>Saccharin sodium</td>
<td>Sodium starch glycollate</td>
<td>Sodium starch glycollate</td>
</tr>
<tr>
<td>Orange flavour</td>
<td>Microcrystalline cellulose</td>
<td>Microcrystalline cellulose</td>
</tr>
<tr>
<td>Vanilla flavour</td>
<td>Sodium saccharin</td>
<td>Sunset yellow lake</td>
</tr>
<tr>
<td>Passion fruit flavour</td>
<td>Magnesium stearate*</td>
<td>Sodium saccharin</td>
</tr>
<tr>
<td>Purified water</td>
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</tbody>
</table>

* 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.

Nature and Contents of Container
Tablets: Blister packs.
Suspensions: Glass/plastic bottle with aluminium cap.

Instructions for Use/Handling
Suspensions: Shake well before use.

Not all presentations are available in every country.

Version number: GDS20/IPI04

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