A large number of clinical studies were used to determine the frequency of very common to rare undesirable effects. This causes the disruption of the helminth metabolism, in inhibiting tubulin polymerisation. It is thought to exert its antihelmintic activity by death of the parasite within the brain. Signs may occur as a result of an inflammatory reaction caused by death of the parasite within the brain. Treatment with ZENTEL may uncover pre-existing neurocysticercosis, particularly in areas with high taeniosis infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal

### Indications

ZENTEL is a benzimidazole carbamate with anthelmintic and anti-protocol activity against the following intestinal and tissue parasites: Roundworm (Ascaris lumbricoides), pinworm (Enterobius vermicularis), hookworm (Necator americanus, Ancylostoma duodenale), whipworm (Trichuris trichiura), threadworm (Strongyloides stercoralis), tape worm (Taenia spp and Hymenolepis nana only in the case of associated parasitism), Clonorchiasis (Clonorchis sinensis), Opisthorchiasis (Opisthorchis viverrini) and cutaneous larva migrans; Giardiasis (G. lambia, G. duodenalis, G. intestinalis, Lambia intestinalis) in children.

### Dosage and Administration

**Dosage**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Dose</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roundworm</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>
</tr>
<tr>
<td>Pinworm*</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Hookworm</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Whipworm</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Strongyloidiasis</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Taeniasis</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Hymenolepiasis</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Clonorchiasis</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Opisthorchiasis</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg (two above)</td>
</tr>
<tr>
<td>Cutaneous larva migrans</td>
<td>Adults and children over 2 years of age.</td>
<td>400 mg</td>
</tr>
<tr>
<td>Giardiasis</td>
<td>Children 2 – 12 years of age only.</td>
<td>400 mg (two above)</td>
</tr>
</tbody>
</table>

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

—in cases of proven Hymenolepiasis, retreatment in 10 to 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, ZENTEL 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.

### Hematologic 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.

### 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 its metabolites).

### 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 taeniosis 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. Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and it is thought to exert its anthelmintic activity by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

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

There have been no studies to investigate the effect of ZENTEL on driving performance or the ability to operate machinery. However, when driving vehicles or operating machinery, it should be taken into account that dizziness has been reported after using ZENTEL (see Adverse Reactions).

### 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:

| Common | ≥ 1/100 |
| Rare | <1/1000 |
| Common | ≥ 1/1000 to <1/10 |
| Rare | <1/10000 |
| Very rare | <1/10000 |

### 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

### Overdose

**Treatment**

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

### Pharmacological Properties

#### Pharmacodynamics

**ATC Code**

P02CA03

**Mechanism of Action**

Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and it is thought to exert its anthelmintic effect by inhibiting tubulin polymerisation. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

### Pharmacokinetics

**Absorption**

In man, albendazole is poorly absorbed (less than 5%) following oral administration.

The systemic pharmacological effect of albendazole is augmented if the dose is administered with a fatty meal, which enhances the absorption by approximately five-fold.

**Distribution**

Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulfoxide, has been reported to achieve plasma concentrations from 1.6 to 6.0 micromol/l, when taken with breakfast.

**Metabolism**

Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulfoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections.

### ZENTEL Qualitative and Quantitative Composition

Tablet containing either 200 mg or 400 mg albendazole.

4 % w/s suspension to be taken orally; 4 g albendazole per 100 mL.

2 % w/s suspension to be taken orally; 2 g albendazole per 100 mL.

### Pharmaceutical Form

Tablet.

Suspension.
Elimination
The plasma half life of albendazole sulfoxide is 8.5 hours. Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

Special Patient Populations

Elderly
Although no studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics, data in 26 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>
<th>Suspension (2%, 4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>Lactose</td>
<td>Aluminium magnesium silicate</td>
<td></td>
</tr>
<tr>
<td>Maize starch</td>
<td>Maize starch</td>
<td>Glycerin</td>
<td></td>
</tr>
<tr>
<td>Polyvidone</td>
<td>Sodium lauryl sulphate</td>
<td>Carboxymethylcellulose sodium</td>
<td></td>
</tr>
<tr>
<td>Sodium lauryl sulphate</td>
<td>Crossmelllose sodium</td>
<td>Polysorbate 80</td>
<td></td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>Povidone K30</td>
<td>Sorbitan monolaureate</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Sodium lauryl sulphate</td>
<td>Potassium sorbate</td>
<td></td>
</tr>
<tr>
<td>Sodium saccharin</td>
<td>Sunset yellow lake</td>
<td>Benzoin acid (see Warnings and Precautions)</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate*</td>
<td>Sodium saccharin</td>
<td>Sorbic acid</td>
<td></td>
</tr>
<tr>
<td>Film coating</td>
<td>Magnesium stearate*</td>
<td>Silicone antifoam 1510</td>
<td></td>
</tr>
<tr>
<td>Methylhydroxypropylcellulose 15</td>
<td>Flavourings</td>
<td>Flavourings</td>
<td></td>
</tr>
<tr>
<td>Methylhydroxypropylcellulose 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol.</td>
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<td></td>
<td></td>
</tr>
</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. The shelf-life depends on the locally registered storage conditions (refer to the pack for information).
Suspensions: Store below 30°C and protect from direct sunlight.

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.

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