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SCHEDULING STATUS:

S2

1.NAME OF THE MEDICINE:

ZENTEL 400 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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

Contains sugar (lactose): 107 mg/tablet.

Contains sweetener (sodium saccharin): 2 mg/tablet.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

ZENTEL 400 Tablets:

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.

4. CLINICAL PARTICULARS:
4.1 Therapeutic indications:

ZENTEL 400 is indicated in the treatment indicated in the treatment of single or mixed intestinal parasites – roundworm; whipworm; pinworm; hookworm; tapeworm, for single dose use.

4.2 Posology and method of administration:

Posology:

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

Note:

If the patient is still symptomatic after a single course of treatment , they must consult a healthcare professional for further treatment. No special procedures, such as fasting or purging, are required. Do not exceed the maximum daily dose and treatment duration recommended. Not to be used in children aged under 1-year.

Elderly:

Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required; however, ZENTEL 400 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 ZENTEL 400 therapy should be carefully monitored.

4.3 Contraindications:

ZENTEL 400 should not be administered during pregnancy or in women thought to be pregnant (see section 4.6).

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

4.4 Special warnings and precautions for use:

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 neurocysticercosis 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. Patients experiencing such symptoms, after taking this medicine must seek advice from a healthcare professional.

Excipient warnings:

Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ZENTEL 400. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus. ZENTEL 400 tablets contain sunset yellow FCF (E110 or FD&C Yellow No 6) which may cause allergic-type reactions.

4.5 Interaction with other medicinal products and other forms of interaction:

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.

4.6 Fertility, pregnancy and lactation:

Pregnancy*:*

ZENTEL 400 should not be administered during pregnancy or in women thought to be pregnant (refer to section 4.3).

Albendazole is known to be teratogenic and embryotoxic in animals.

Breastfeeding:

Adequate human data during lactation are not available.

4.7 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.

4.8 Undesirable 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 to < 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.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZENTEL 400.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (refer to section 4.8).

5. PHARMACOLOGICAL PROPERTIES:

A 12 Anthelmintics ATC Code P02CA03

5.1 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 polymerisation. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

5.2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Excipients: lactose, microcrystalline cellulose, maize starch, croscarmellose sodium, povidone, sodium lauryl sulphate, FD&C yellow no 6 aluminium lake, sodium saccharin, magnesium stearate and flavourings (orange, passion fruit and vanilla).

6.2 Incompatibilities:

Not applicable

6.3 Shelf life

60 months

6.4 Special precautions for storage:

Keep out of reach of children.

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

6.5 Nature and contents of the container:

ZENTEL 400 tablets are available in blister pack strips of one tablet each packed in an outer carton or plastic securitainers containing 100 or 500 tablets

7. HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1

7460

8. REGISTRATION NUMBER:

30/12/0354

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION:

22 January 1997

10. DATE OF REVISION OF TEXT:

26 April 2024

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