



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. Name of the Medicinal Product

- (a) Product Name : Alzel -400 Tablets (Albendazole Tablets)
(b) Strength : 500 mg
(c) Pharmaceutical Dosage Form : Tablets

2. Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Composition:

Each uncoated tablet contains:
Albendazole B.P. 400 mg

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Specification	Label Claim	Quantity (mg/Tablet)	Active/ Inactive
1	Albendazole	B.P.	400 mg	404.0 mg	Active

3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.: Orange colour, oblong biconvex shape and uncoated tablet. One side plain & other side mid break line.

4. Clinical Particulars

4.1 Therapeutic Indications:

Alzel-400 Tablet is indicated in the treatment of single or mixed invasion caused by threadworm human whipworms human, human worm, hookworm duodenal, American hookworm, tapeworm and nematode intestinal tapeworm unarmed and armed.

4.2 Posology and method of administration:

Hydatid Disease:

For 60 kg or above body weight- 400 mg twice daily with meals
For less than 60 kg body weight-15 mg/kg/day given in divided doses twice daily with meals (maximum total daily dose 800 mg)

Duration: 28-day cycle followed by a 14-day albendazole-free interval, for a total of 3 cycles
NOTE: When administering Alzel-400 Tablet in the pre- or post-surgical setting, optimal killing of cyst contents is achieved when 3 courses of therapy have been given.

Neurocysticercosis:

For 60 kg or above body weight- 400 mg twice daily with meals
For less than 60 kg body weight-15 mg/kg/day given in divided doses twice daily with meals (maximum total daily dose 800 mg)

Duration: 8-30 days

Method of administration:

Alzel-400 Tablets can be taken by oral route only.

4.3 Contraindications:

Hypersensitivity to any component of the formulation or suspected pregnancy. In women of childbearing potential use of the drug is limited to the first 7 days after the onset of menstruation or after obtaining a negative pregnancy test.

Do not use in children under 2 years of age.

Treatment with albendazole may disclose CNS cysticercosis, before extending symptoms, neurological symptoms (convulsions, increased intracranial pressure, focal symptoms) may occur soon after treatment, immediately start administering anticonvulsants and steroids.

4.4 Special warning and precautions for use:

Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported.

Hypersensitivity reactions including rash, pruritus and urticaria have been reported less frequently.

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

Concurrent use of dexamethasone, praziquantel or cimetidine increases the plasma concentrations of albendazole.

The drugs carbamazepine, phenytoin, and phenobarbital lower the plasmatic concentration and the half-life of albendazole.

Ritonavir, phenytoin, carbamazepine and phenobarbital may decrease concentrations of the active metabolite of albendazole in serum; significance of this interaction is unknown, however, because of the risk of reducing the effectiveness of the drug should monitor the effectiveness of treatment, particularly when treating systemic infections and, if necessary, modify the dosage.

4.6 Pregnancy and lactation:

Pregnancy:

Category C: Do not use during pregnancy.

Albendazole has harmful effects on the fetus and causes developmental defects in animals. In the course of treatment and one month after its completion should use effective methods of contraception.

In women of childbearing age, treatment should be carried out during the first 7 days of menstruation or after a negative pregnancy test.

Lactation:

Should not be used during breastfeeding unless the potential benefits outweigh the risks of treatment.

4.7 Effects on ability to drive and use machine:

Albendazole has no influence on the ability to drive and use machines.

4.8 Undesirable effects:

Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported.

Hypersensitivity reactions including rash, pruritus and urticaria have been reported less frequently.

4.9 Overdose:

If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: Anthelmintics, benzimidazoles derivatives

ATC code: P02CA03

Albendazole is a broad-spectrum anthelmintic. The principal mode of action for albendazole is by its inhibitory effect on tubulin polymerization which results in the loss of cytoplasmic microtubules.

Albendazole causes degenerative alterations in the tegument and intestinal cells of the worm by binding to the colchicine-sensitive site of tubulin, thus inhibiting its polymerization or assembly into microtubules. The loss of the cytoplasmic microtubules leads to impaired uptake of glucose by the larval and adult stages of the susceptible parasites, and depletes their glycogen stores. Degenerative changes in the endoplasmic reticulum, the mitochondria of the germinal layer, and the subsequent release of lysosomes result in decreased production of adenosine triphosphate (ATP), which is the energy required for the survival of the helminth. Due to diminished energy production, the parasite is immobilized and eventually dies.

5.2 Pharmacokinetic Properties:

Absorption

In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed (<5%) with most of an oral dose remaining in the gastrointestinal tract. The poor absorption is believed to be due to the low aqueous solubility of albendazole. Absorption is significantly enhanced (up to 5 fold) if albendazole is administered with a fatty meal compared with fasted state.

Distribution

Albendazole sulfoxide is widely distributed throughout the body including into urine, bile, liver, cyst wall, cyst fluid, and cerebrospinal fluid (CSF). It is about 70% bound to plasma protein.

Metabolism

Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma or in urine. Albendazole sulphoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections (anthelmintic activity). Peak plasma concentrations of albendazole sulfoxide attained 2–5 hours after a dose. Albendazole sulphoxide is further metabolized to albendazole sulfone and other primary oxidative metabolites.

Elimination

Albendazole sulphoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion (<1% of albendazole sulfoxide) appearing in the urine. The plasma half-life of albendazole sulphoxide is 8-12 hours.

Special population

Patients with extrahepatic obstruction: Increased albendazole sulfoxide serum concentration and prolonged half-life. Elimination half-life may be 31.7 hours.

5.3 Preclinical Safety Data:

No relevant data available.

6. Pharmaceutical Particulars

6.1 List of Excipients:

Sr. No.	Name of the Materials
1	Maize Starch
2	Microcrystalline Cellulose
3	Gelatin
4	Methylparaben Sodium
5	Magnesium Stearate
6	Purified Talc
7	Colloidal Silicon Dioxide
8	Sodium Saccharin
9	Sodium Starch Glycolate
10	Flavour Orange
11	Colour Sunset Yellow Supra

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

36 Months

6.4 Special precautions for storage:

Store in a cool, dark & dry place.

6.5 Nature and contents of container:

1 × 1 Tablet Alu-PVC Blister pack.

6.6 Instructions for use and handling

No special requirements.

7. Applicant/Manufacturer

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