General Info

Brand name: ZENTEL 400 MG TAB

Generic Name: ALBENDAZOLE

Drug Code: ZENT002

Category Information

ANTIPARASITIC AGENTS

Subcategory Information

ANTHELMINTIC

General Info
Indications
Dosing
Mechanism Of Action
Pharmacokinetics
Contraindications
Interactions
Adverse Effects
Monitoring Parameters
Pregnancy & Lactation
Special Precautions

DOSING

Adult Dosing

Hydatid disease (Echinococcus granulosis, dog tapeworm)

Oral

- < 60 kg: 15 mg/kg/day in 2 divided doses (maximum: 800 mg/day).
- ≥60 kg: 800 mg/day in 2 divided doses.
- Duration: Optimal duration uncertain; 1 to 6 months based on clinical factors

Neurocysticercosis (Taenia solium, pork tapeworm), parenchymal disease

Oral

- 15 mg/kg/day in 2 divided doses for 10 to 14 days.
- Max: 1.2 g/day; may be repeated if persistent viable lesions on 6-month follow-up imaging.
- Note: Concomitant therapy with praziquantel is recommended if >2 viable cysts present. Initiate adjunctive corticosteroid therapy prior to initiation of albendazole. Before initiating therapy for neurocysticercosis, examine the patient for the presence of retinal lesions.

Enterobiasis/ Hookworm infections/ Trichuriasis/ Ascariasis(off-label use)

Oral

- 400 mg as a single dose; repeat in 2 weeks.

Clonorchiasis/ Opisthorchiasis/ Cutaneous larva migrans(off-label use)

Oral

- 400 mg bid for 3 days. Max: 800 mg daily; 1,200 mg for 3 days.

COUNSELLING

- Albendazole should be taken with food. Administer with a high-fat meal for systemic infections to increase absorption.
- Administration on an empty stomach may be appropriate for treating an intraluminal infection with no systemic involvement.
- If patients have difficulty swallowing, tablets may be crushed or chewed, then swallowed with a drink of water.
- This drug may cause dizziness, if affected, do not drive or operate machinery.
- Maintain strict hygiene.
- During albendazole therapy, because of the possibility of harm to the liver or bone marrow, routine (every 2 weeks) monitoring of blood counts and liver function tests should take place.
- Albendazole may cause fetal harm, therefore, women of childbearing age should begin treatment after a negative pregnancy test.
- Women of childbearing age should be cautioned against becoming pregnant while on albendazole or within 1 month of completing treatment.

INDICATION

- Hydatid disease (Echinococcus granulosus, dog tapeworm)
- Neurocysticercosis (Taenia solium, pork tapeworm), parenchymal disease
- Enterobiasis Hookworm infections Trichuriasis Ascariasis(off-label use)
- Clonorchiasis Opisthorchiasis Cutaneous larva migrans(off-label use)
- Giardiasis (Giardia duodenalis) (alternative agent) (off-label use)

INTERACTION

Generic-Generic

ALBENDAZOLE - PHENOBARBITONE
Risk Type: C (Monitor Therapy)
Details : May decrease serum concentrations of the active metabolite(s) of Albendazole.

Generic-Generic

ALBENDAZOLE - PHENYTOIN
Risk Type: C (Monitor Therapy)
Details : May decrease serum concentrations of the active metabolite(s) of Albendazole.

Generic-Generic

ALBENDAZOLE - CARBAMAZEPINE
Risk Type: C (Monitor Therapy)
Details : May decrease serum concentrations of the active metabolite(s) of Albendazole.

ADVERSE EFFECTS

Blood and lymphatic system disorders

- Leukopenia, neutropenia.

Eye disorders

- Blurred vision.

Gastrointestinal disorders

- Abdominal pain, nausea, vomiting, diarrhea.

Hepatobiliary disorders

- Mild to moderate hepatic enzyme elevation, hepatitis, acute liver failure.

Musculoskeletal and connective tissue disorders

- Rhabdomyolysis

Nervous system disorders

- Headache, dizziness, somnolence, convulsion.

Renal and urinary disorders

- Acute renal failure.

CONTRAINDICATION

- Hypersensitivity to albendazole, benzimidazoles, or any component of the formulation.

MECHANISM OF ACTION

- Inhibits microtubule formation by binding to colchicine sensitive site of β-tubulin resulting to decrease in microtubules leading to decline in glucose uptake, absorptive function and depletion of glycogen storage by adult and larval forms of parasites.

- Insufficient glucose causes lack of ATP resulting to death of parasite.

MONITORING PARAMETER

Parameters

- LFTs and CBC (each 28-day cycle and every 2 weeks during therapy).
- Assess faecal specimens for ova and parasites for 3 weeks after treatment.
- Obtain baseline ophthalmic exam for retinal lesions.
- Monitor for cerebral hypertension, focal neurologic deficits, or seizures after initiation of therapy and obtain pregnancy test during treatment.

OVERDOSAGE

Symptoms

- Diarrhea, vomiting, increased heart rate and breathing difficulties.

Management

- Symptomatic therapy and general supportive measures are recommended.

PHARMACOKINETICS

Absorption

Poorly absorbed in the gastrointestinal tract. Increased serum concentration with a fatty meal.

- Onset: 2 hours
- Duration: 24 hours
- Peak plasma conc.: 2-5 hours

Distribution

Widely distributed throughout the body including urine, bile, liver, cyst wall, cyst fluid and CSF. Enters breast milk

- Plasma protein binding: 70%.

Metabolism

- Hepatic; extensive first-pass effect; pathways include rapid sulfoxidation to active metabolite, hydrolysis, and oxidation

Elimination

Via urine (<1% as active metabolite); faeces.

- Elimination half-life: 8-12 hrs

PREGNANCY

- Category C (Risk Cannot be ruled Out)
- Albendazole has been shown to be teratogenic (to cause embryotoxicity and skeletal malformations) in pregnant rats and rabbits. (Unknown Category)
- Albendazole should not be used in pregnant women except in clinical circumstances where no alternative management is appropriate. (Unknown Category)
- Patients should not become pregnant for at least 1 month following cessation of albendazole therapy. If a patient becomes pregnant while taking this drug, albendazole should be discontinued immediately. (Unknown Category)

LACTATION

- Concentrations of albendazole and the active metabolite, albendazole sulfoxide, have been reported to be low in human breast milk.
- There are no reports of adverse effects on the breastfed infant and no information on the effects on milk production.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for albendazole and any potential adverse effects on the breastfed infant from albendazole or from the underlying maternal condition.

SPECIAL PRECAUTIONS

Risk of Neurologic Symptoms in Neurocysticercosis

› Patients being treated for neurocysticercosis should receive steroid and anticonvulsant therapy to prevent 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.

Bone marrow suppression

› Agranulocytosis, aplastic anemia, granulocytopenia, leukopenia, and pancytopenia have occurred leading to fatalities (rare); use with caution in patients with hepatic impairment (more susceptible to hematologic toxicity). Discontinue therapy in all patients who develop clinically significant decreases in blood cell counts.

Transaminase elevations

› Reversible elevations in hepatic enzymes have been reported. Patients with abnormal LFTs and hepatic echinococcosis are at an increased risk of hepatotoxicity. Discontinue therapy if LFT elevations are >2 times the upper limit of normal; may consider restarting treatment (with frequent monitoring of LFTs) when hepatic enzymes return to pretreatment values. Discontinue therapy if hepatic enzymes are significantly increased.

Pregnancy and Lactation

› Albendazole may cause fetal harm, therefore, women of childbearing age should begin treatment after a negative pregnancy test.