

BALZOLE
Albendazole Tablets 400 mg

INN:

Albendazole

Description:

It contains Albendazole as active ingredients. The empirical formula of Albendazole [Methyl [5-(propylsulfanyl)-1H-benzimidazol-2-yl]carbamate] is $C_{12}H_{15}N_3O_2S$ and molecular weight is 265.3 g/mol.

Composition:

Each uncoated chewable tablet contains

Albendazole BP 400 mg

Excipients q.s.

Colour : Sunset Yellow

Pharmaceutical Form:

Chewable Tablets

Pharmacotherapeutic group and ATC code:

Anthelmintics, Antinematodal agents, Benzimidazole derivative; ATC Code: P02CA03

Indication:

Albendazole' is a benzimidazole carbamate anthelmintic for use in the treatment of hydatid cysts caused by:

Echinococcosis:

Albendazole Tablets shows greatest efficacy in the treatment of liver, lung and peritoneal cysts. Experience with bone cysts and those in the heart and central nervous system is limited.

Cystic Echinococcosis (caused by *Echinococcus granulosus*)

Albendazole Tablets is used in patients with cystic echinococcosis:

1. Where surgical intervention is not feasible.
2. Prior to surgical intervention.
3. Post-operatively if pre-operative treatment was too short, if spillage has occurred or if viable material was found at surgery.
4. Following percutaneous drainage of cysts for diagnostic or therapeutic reasons.

Alveolar Echinococcosis (caused by *Echinococcus multilocularis*)

Albendazole Tablets is used in patients with alveolar echinococcosis:

1. In inoperable disease, particularly in cases of local or distant metastasis.
2. Following palliative surgery.
3. Following radical surgery or liver transplantation.

Pharmacological Properties:

Pharmacodynamics: Albendazole is a benzimidazole carbamate with anthelmintic effects against tissue parasites.

Albendazole exhibits larvicidal, ovicidal and vermucidal 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.

Albendazole is effective in the treatment of tissue parasites including cystic echinococcosis and alveolar echinococcosis caused by infestation of *Echinococcus granulosus* and *Echinococcus multilocularis*, respectively.

Pharmacokinetics: In man, albendazole is poorly absorbed (<5%) following oral administration. 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. The plasma half-life of albendazole sulfoxide is 8½ hours. 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/litre when taken with breakfast. When the dose is administered with a fatty meal, which enhances the absorption by approximately 5-fold.

Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

Posology and Method of administration:

Dosages are dependent on the parasite involved, the weight of the patient, and the severity of the infection, so use as directed by physician.

For oral use. The tablet should be chewed

Side effect:

Very common: Mild to moderate elevations of hepatic enzymes, Headache

Common: Dizziness, gastrointestinal disturbances, reversible alopecia, fever

Contraindication:

Albendazole should not be administered during pregnancy or in women thought to be pregnant. Women of childbearing age should be advised to take effective precautions, with non hormonal contraceptive measures, against conception during and within one month of completion of treatment with Albendazole Tablets.

Drug interaction:

Drugs that can reduce the effectiveness of albendazole – Anticonvulsants (eg phenytoin: fosphenytoin: carbamazepine: phenobarbital: primidone), Levamisole, Ritonavir.

Drugs that may increase levels of the active metabolite of albendazole – monitor to possible increased albendazole adverse effects i.e Cimetidine, Dexamethasone (continuous use raises albendazole levels by 50%), Praziquantel.

Grapefruit juice also increases the plasma levels of albendazole sulfoxide.

Theophylline Care should be exercised when albendazole is given to patients taking these medicines.

Warning and Precaution:

Albendazole has been associated with mild to moderate elevations of hepatic enzymes, if their level increased (greater than twice the upper limit of normal), albendazole should be discontinued. Treatment may be restarted when hepatic enzymes have returned to normal limits, but patients should be monitored for recurrence. Albendazole has been shown to cause bone marrow suppression and it should be discontinued if clinically significant decreases in blood cell counts occur.

Precautions:

Care and precautions should be taken during usage of albendazole in pregnancy, Oral or intravenous corticosteroids are recommended to prevent cerebral hypertensive episodes during the first week of treatment. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

Tablet to be chewed.

Usage during pregnancy, lactation and driving:

Albendazole Tablets 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 albendazole Tablets should not be used during lactation.

Dizziness is reported as a common reaction. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where this could put them or others at risk.

Overdose and Treatment:

In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

Storage condition:

Do not store above 30°C.

KEEP OUT OF THE REACH OF CHILDREN

Prescription Only Medicine

Manufactured by:

Rhyburg Pharmaceuticals Ltd.

C2 & 3, S.I.E.L., Selaqui,

Dehradun, Uttarakhand (India)

website : www.rplglobal.com