pharmaniaga®

IDAMAN PHARMA ALBENDAZOLE SUSPENSION 200MG/ 5ML

DESCRIPTION
Uniform, opaque, mobile, viscous liquid white to beige coloured, fruit flavoured suspension, free from visible impurities.

Each 5ml of suspension contains Albendazole 200mg
Preservatives:
Methyl Paraben: 10mg
Propyl Paraben: 2.5mg

ROUTE OF ADMINISTRATION
Oral

PHARMACODYNAMICS
Albendazole is a benzimidazole carbamate anthelmintic drug similar to mebendazole. It is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths including a variety of intestinal nematodes, cestodes, and trematodes. It is also effective against tissue helminth infections, such as cutaneous larva migrans and has also been used in the high dose, long term treatment of tissue helminth infections including hydatid cysts and cysticercosis.

The antihelminthic action of albendazole is thought to be mainly intra-intestinal due to low absorption (less than 5%) after oral administration. However, at higher albendazole doses, sufficient amount is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites.

Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to act via inhibition of tubulin polymerization. This causes a cascade of metabolic disruption, including energy depletion, which immobilizes and then kills the susceptible helminth.

PHARMACOKINETICS
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.

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.

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.

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.

INDICATIONS
Treatment of single or mixed infestations of intestinal parasites.

RECOMMENDED DOSAGE
For roundworm, whipworm, hookworm and pinworm
- Adults and children above 24 months: 1 bottle (400mg) as a single dose.
- Children 12-24 months: Take half the adult dose.

For threadworm and tapeworm
- Adults and children above 24 months: 1 bottle (400mg) as a single dose once a day for 3 consecutive days.
- Not to be used in children aged under 1 year.

CONTRAINDICATIONS
Should not be administered during pregnancy or in women thought to be pregnant as it has been shown to be teratogenic and embryotoxic in some animals.
Contraindicated in persons who are known to be hypersensitive to albendazole, other benzimidazole derivatives, or any component of product.

WARNINGS AND PRECAUTIONS
General precaution:
Confirmation of eradication of many intestinal and tissue parasites is necessary after treatment.

Use in Systemic Helminth Infections (longer duration of treatment at higher doses)

Hepatic Effects:
Mild to moderate elevations of liver enzymes have been reported with albendazole. Elevations of liver enzymes increase risk of hepatotoxicity and bone marrow suppression. In prolonged higher dose albendazole therapy for hydatid disease, there have been rare reports of severe hepatic abnormalities associated with jaundice and histological hepatocellular damage, which may be irreversible. Case reports of hepatitis have also been received. Enzyme abnormalities usually normalise on discontinuation of treatment. Monitor and perform liver function tests (hepatic transaminase concentrations) prior to each cycle of albendazole treatment and at least every 2 weeks during treatment. If liver enzymes are significantly increased (greater than twice the Upper Limit of Normal (ULN) or full blood count decreases by a clinically significant level, consider discontinuing the drug based. Decisions to reinstitute albendazole when hepatic enzymes return to pre-treatment levels should be individualized taking into account the risks and benefits of further albendazole treatment. If the drug is reinstituted, perform laboratory tests frequently to monitor for recurrence.

Myelosuppression:
Can caused bone marrow suppression, aplastic anemia and agranulocytosis in patients with or without underlying hepatic dysfunction. Reversible leukopenia has occurred in <1% of patients receiving the drug; granulocytopenia, pancytopenia, agranulocytosis, or thrombocytopenia reported rarely. Rare fatalities reported due to granulocytopenia or pancytopenia. Albendazole has been shown to cause bone marrow suppression and therefore blood counts should be monitored at the start of each 28- day cycle and every two weeks during treatment. Closer monitoring of blood counts is recommended in patients with liver disease, including hepatic echinococcosis, since these individuals may be more susceptible to bone marrow suppression leading to pancytopenia, aplastic anemia, agranulocytosis, and leukopenia. Albendazole should be discontinued if clinically significant decreases in blood cell counts occur.

Precautions Related to Treatment of Neurocysticercosis:
Destruction of cysticercosis lesions by albendazole may cause irreparable retinal damage, even when corticosteroids are given. Prior to treatment of neurocysticercosis, examine patient for cysticercosis retinal lesions. In those with such lesions, weigh the need for treatment against the possibility of irreparable retinal damage.

Symptoms associated with an inflammatory reaction following death of the parasite within the brain may occur in patients receiving albendazole treatment for neurocysticercosis (e.g. seizures, raised intracranial pressure, hydrocephalus, focal signs). These should be treated with appropriate corticosteroid and anticonvulsant therapy. Oral or intravenous corticosteroids are recommended during the first week of treatment to prevent cerebral hypertension. Pre-existing neurocysticercosis may also be uncovered in patients treated with albendazole for other conditions. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

There is a risk that treatment of *Taenia solium* infections may be complicated by cysticercosis and appropriate measures should be taken to minimise this possibility.

Use in Impaired Renal or Hepatic Function:
The use in patients with impaired renal or hepatic function has not been studied. However, caution should be used in patients with pre-existing liver disease, since albendazole is metabolised by the liver and has been associated with idiosyncratic hepatotoxicity.

Use in Children:
There is limited experience in children under 2 years of age, therefore use in this age group is not recommended.

INTERACTION WITH OTHER MEDICAMENTS
Cimetidine, praziquantel and dexamethasone have been reported to increase the plasma levels of the albendazole active metabolite. Grapefruit juice may increase the bioavailability of albendazole but less than the increase observed after a fatty meal.

Phenytoin, carbamazepine, and phenobarbital appear to induce the oxidative metabolism of albendazole, resulting in significantly reduced concentrations of albendazole sulfoxide. This interaction is likely to be clinically significant when albendazole is used to treat systemic worm infections. The interaction is probably not clinically significant when albendazole is used for intestinal worm infections.

Chinese Ginseng may theoretically reduce the intestinal concentration of albendazole active metabolite.

Albendazole may theoretically inhibit theophylline metabolism and increase toxicity.

PREGNANCY AND LACTATION
Pregnancy
SHOULD NOT BE ADMINISTERED DURING CONFIRMED OR SUSPECTED PREGNANCY.

Lactation
Adequate human and animal data on use during lactation are not available. Therefore, breast-feeding should be discontinued during and for a minimum of 5 days after treatment.

SIDE/ADVERSE EFFECTS
Adverse effects are usually mild and resolve without treatment.

Dermatologic Effects:
Reversible alopecia (thinning of hair, and moderate hair loss), itchiness and/or skin rashes, erythema multiforme and Stevens-Johnson syndrome.

Gastrointestinal Effects:
Abdominal pain, diarrhoea, nausea and vomiting.

Hematologic Effects:
Low red cell count, leucopenia, pancytopenia, aplastic anaemia and agranulocytosis.

Hepatic Effects:
Transiently raised hepatic enzymes, hepatitis, acute liver failure, jaundice and hepatocellular damage.

Immunologic Effects:
Hypersensitvity reaction such as rash, pruritis and urticarial.

Neurologic Effects:
Dizziness, headache, symptoms associated with treatment for neurocysticercosis (e.g. seizures, raised intracranial pressure, hydrocephalus, focal signs).

Ophthalmic Effects:
Albendazole induced retinal damage in patients with pre- existing cysticercosis retinal lesions.

Renal Effects:
Proteinuria

Others:
Bone pain and fever

SYMPTOMS AND TREATMENT OF OVERDOSE
Overdosage has not been observed in humans. Recommendations for treatment of overdosage are the usual measures to remove the unabsorbed materials from the gastro-intestinal tract and supportive therapy for the evolving clinical syndrome.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
Not applicable.

STORAGE CONDITIONS
Store below 30°C in a cool dry place, Protect from light.

INSTRUCTIONS FOR USE
Shake well before use.

PACKING SIZES
PET Plastic Container of 10ml.

SHELF LIFE
Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NUMBER
MAL19988504XZ

KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

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Lt-149.08 Product Registration Holder and Manufacturer

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