Bharat Parenterals Limited
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CIN NO: U24231GJ1992PLC018237

ASCANTEL - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Albendazole Oral Suspension

Trade Name:

ASCANTEL

1.2 Strength:

Each 5 ml contains

Albendazole USP.... ....200 mg

Flavoured syrup base ...q.s.

Colour: Sunset Yellow FCF

1.3 Pharmaceutical form:

Oral Liquid

2. Qualitative and Quantitative Composition:

Sr. No	Name of Material	Spec.	Qty./ 5 ml of suspension (mg)	Qty./ Bottle of suspension (gm)	Qty. Taken as per Batch Size (Kg.)	Function
1.	Albendazole	USP	200.00	0.400	6.660	Active
2.	Sodium Methyl Paraben	BP	5.00	0.010	0.167	Preservative
3.	Sodium Propyl Paraben	BP	2.50	0.005	0.083	Preservative
4.	Citric Acid Monohydrate	BP	7.50	0.015	0.250	Buffering Agent
5.	Sucrose (Refined Sugar)	BP	2500.00	5.000	83.330	Sweetener
6.	Sodium carboxy methyl cellulose	BP	25.00	0.050	0.833	Suspending agent
7.	Polysorbate – 80	BP	7.50	0.015	0.250	Stabilizing agent
8.	Anhydrous Colloidal Silica	BP	15.00	0.03	0.500	Anti- Caking Agent
9.	Color Sunset Yellow Supra	IH	1.00	0.002	0.033	Coloring agent
10.	Flavor Orange Sweet	IH	75.00	0.15	0.033	Flavoring agent
11.	Purified Water	BP	Q. S.	Q. S.	Q. S.	Vehicle

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3. Pharmaceutical form:

Dosage Form: Oral-Liquid

Visual & Physical characteristics of the product:.

Albendazole Oral Suspension

Description: An orange coloured suspension filled in an amber colour Pet bottle.

Type of container & closure System:

15 ml amber colour Pet bottle.

4. Clinical particulars:

4.1 Therapeutic indications

Indicated in the treatment of single or mixed infestations of the following:

Enterobius vermicularis (pinworm/threadworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* and *Necator americanus* (hookworms), *Trichuris trichiura* (whipworm), *Strongyloides stercoralis*, animal hookworm larvae causing cutaneous larva migrans, and the liver flukes *Opisthorchis viverrini* and *Clonorchis sinensis*.

It is also indicated for the treatment of Hymenolepis nana and Taenia spp. (tapeworm) infections, when other susceptible helminths species are present.

Albendazole is indicated in giardiasis in children over 2 years of age.

Albendazole in higher doses is indicated for the treatment of hydatid disease.

4.2 Posology and method of administration

Age 12 to 24 months: 200 mg as a single dose.

Adults & children (over two years): 400 mg as a single dose in cases of *Enterobius vermicularis, Trichuris trichiura, Ascaris lumbricoides, Ancylostoma duodenale* and *Necator americanus*. In cases of strongyloidiasis or taeniasis, 400 mg as a single dose should be given for three consecutive days.

Giardiasis: 400 mg once daily for five days.

In hydatid disease (Echinococcosis): In the treatment of echinococcosis, it is given by mouth with meals in a dose of 400 mg twice daily for 28 days for patients weighing over 60 kg. A dose of 15 mg/kg body weight daily in two divided doses (to a maximum total daily dose of 800 mg) is used for patients weighing less than 60 kg. For cystic echinococcosis the 28- days course may be repeated after 14 days without treatment to a total of three treatment cycles. For alveolar echinococcosis, cycles of 28 days of treatment followed by 14 days without

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treatment may need to continue for months or years. When three courses of therapy have been given in the pre or post surgical setting, optimal killing of cyst contents is achieved.

4.3 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.

4.4 Special warnings and precautions for use

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 decreased by a clinically significant level, consider discontinuing the drug based. Decisions to reinstitute albendazole when hepatic enzymes return to pretreatment 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 cause 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

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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 albendazsole is metabolised by the liver and has been associated with idiosyncratic hepatotoxicity.

Use in Children:

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

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Fertility, pregnancy and lactation

Pregnancy: Category C

Albendazole has been shown to be teratogenic (to cause embryotoxicity and skeletal malformations) in pregnant rats and rabbits. The teratogenic response in the rat was shown at oral doses of 10 and 30 mg/kg/day (0.10 times and 0.32 times the recommended human dose based on body surface area in mg/m2, respectively) during gestation days 6 to 15 and in pregnant rabbits at oral doses of 30 mg/kg/day (0.60 times the recommended human dose based on body surface area in mg/m2) administered during gestation days 7 to 19. In the rabbit study, maternal toxicity (33% mortality) was noted at 30 mg/kg/day. In mice, no teratogenic effects were observed at oral doses up to 30 mg/kg/day (0.16 times the recommended human dose based on body surface area in mg/m2), administered during gestation days 6 to 15.

There are no adequate and well-controlled studies of albendazole administration in pregnant women. Albendazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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