

A-Ben DS[®]

Albendazole 400 mg

COMPOSITION:

A-Ben DS Tablet: Each chewable tablet contains Albendazole USP 400 mg.

PHARMACOLOGY:

A-Ben DS (Albendazole) is a benzimidazole antihelmintic, active against most nematodes and some cestodes. It is used in the treatment of intestinal nematode infections and in higher doses in the treatment of hydatid disease. Albendazole exhibits vermifugal, ovicidal, and larvicidal activity. The principal mode of action of Albendazole is its inhibitory effect on tubulin polymerization, which results in the loss of cytoplasmic microtubules.

INDICATION:

A-Ben DS is indicated in single and mixed infestations of : Enterobius vermicularis (Pinworm or threadworm), Trichuris trichiura (Whipworm), Ascaris lumbricoides (Large roundworm), Ancylostoma duodenale (Roundworm), Necator americanus (Hookworm), Taenia spp. (Tapeworm) , Strongyloides stercoralis (Threadworm). Albendazole is used in the treatment of hydatid disease in higher doses.

DOSE & ADMINISTRATION:

Adults or children over 2 years of age: 400 mg (A-Ben DS) 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 (A-Ben DS) as a single dose should be given for 3 consecutive days.

Children under 1 year of age: Albendazole is not recommended .

CONTRA-INDICATION:

Albendazole is contra-indicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of Albendazole.

WARNING AND PRECAUTION:

Elevations in hepatic enzyme levels and reversible reduction in total white cell count have occasionally been reported. These changes appear to be more common during treatment of E. multilocularis.

SIDE EFFECTS:

Gastrointestinal disturbances, headache and dizziness have been reported during treatment. These symptoms are usually mild and resolve without treatment. Rash, fever and rarely alopecia may occur during treatment.

USE IN PREGNANCY & LACTATION:

Use in pregnancy:

US FDA pregnancy category C. Albendazole is contraindicated during pregnancy and for one month prior to conception. In order to avoid administering albendazole during early pregnancy, women of childbearing age (15-45) should initiate treatment during the first week of menstruation or after a negative pregnancy test.

Use in 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.

USE IN CHILDREN & ADOLESCENTS:

A-Ben DS is not recommended children under 2 years of age.

DRUG INTERACTION:

Albendazole has been shown to induce liver enzymes of the cytochrome P-450 system responsible for its own metabolism. There is, therefore, a theoretical risk of interaction with theophylline, anticonvulsants, anticoagulants, oral contraceptives and oral hypoglycemic. Care should therefore be exercised during the introduction of Albendazole in patients receiving the above groups of compounds.

ADVERSE DRUG REACTION:

A few cases of gastrointestinal discomfort and headache have been reported, but no definite relationship with the drug has been shown.

OVERDOSE:

There is no experience of over dosage. Gastric lavage may be performed in the first two to three hours after ingestion. No specific antidote is known. However, symptomatic treatment and general supportive measures should be undertaken as required.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

A-Ben DS Tablet: Each box containing 25x4's tablets in blister pack.



Manufactured by

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