

HEALTHZOLE

Albendazole Tablets USP 400mg

Composition:

Each chewable tablet contains:

Albendazole USP 400 mg

Excipients q.s.

Approved colour used.

Description: HEALTHZOLE contains albendazole, which is methyl [5-(propylthio)-1H -benzimidazol-2-yl] carbamate. It is a member of the benzimidazole group of anthelmintic agents.

Pharmacology: Albendazole therapy has also been used in the high dose, long term treatment of tissue helminth infections including hydatid cysts and cysticercosis. The anthelmintic action of albendazole is thought to be mainly intra-intestinal. However, at higher albendazole doses, sufficient is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermicial 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: In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed 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 (approximately 5 fold) if albendazole is administered with a fatty meal. Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulphoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half life of albendazole sulphoxide is 8½ hours. Albendazole sulphoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

Indications: Single dose or short term courses of HEALTHZOLE are indicated in the treatment of single or mixed infestations of intestinal and tissue parasites, in adults and children over 2 years of age. Clinical studies have shown HEALTHZOLE to be effective in the treatment of infections caused by: *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*. HEALTHZOLE is also indicated for the treatment of *Hymenolepis nana* and *Taenia* spp. (tapeworm) infections, when other susceptible helminths species are present. Treatment courses should be extended to 3 days

Contraindications: HEALTHZOLE should not be administered during pregnancy or in women thought to be pregnant. HEALTHZOLE has been shown to be teratogenic and embryotoxic in rats and rabbits. Women of childbearing age should be advised to take effective precautions against conception during and within one month of completion of treatment with HEALTHZOLE. HEALTHZOLE is contraindicated in persons who are known to be hypersensitive to albendazole, other benzimidazole derivatives, or any component of the tablets.

Precautions: Patient w/ retinal lesions. Patient treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Pregnancy and lactation. Monitoring Parameters Monitor faecal specimens for ova and parasites for 3 wk after treatment; LFTs and CBC w/ differential; ophth exam (patients w/ neurocysticercosis).

Interactions: Increased serum concentrations w/ dexamethasone, praziquantel and cimetidine. Decreased serum concentrations w/ aminoquinoline (antimalarials), carbamazepine, phenobarbital, and phenytoin.

Food Interaction: Increased serum levels w/ a fatty meal. Grapefruit juice may increase serum concentrations of albendazole.

Dosage: As directed by the physician.

Storage: Store below 30°C in a dry place, protect from light.

Keep the medicine out of reach of children

Do not use in pregnancy.

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