

ZOLAT

Albendazole 200mg Tablet
Albendazole 400mg Tablet
Albendazole 400mg Chewable Tablet
Albendazole 100mg/5ml Suspension

COMPOSITION:

The chemical name of Albendazole is methyl [5-(propylthio)-1H-benzimidazol-2-yl] carbamate.

Each Albendazole 200 mg tablet contains 200 mg Albendazole.

Each Albendazole 400mg Tablet / Chewable Tablet contains 400mg Albendazole

The suspension contains 100 mg Albendazole in each 5 mL

PHARMACOLOGICAL ACTION:

Albendazole is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against intestinal and tissue parasites. Animal studies have shown that Albendazole exhibits vermifugal, ovcidal and larvacidal activity and exerts its anthelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth. In man, after oral administration, Albendazole is absorbed and completely metabolized. At a dose of 6,6 mg/kg of Albendazole the plasma concentration of its main metabolite, the sulfoxide, attains a maximum of 0,25 to 0,30 micrograms/mL after approximately 2½ hours. The half-life of the sulfoxide in the plasma is 8% hours. The metabolite is essentially eliminated via the urine,

WARNINGS:

In order to avoid administering Albendazole during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

INDICATIONS:

Albendazole is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown Albendazole is effective in the treatment of *Ascaris lumbricoides* (roundworm), *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm/threadworm), *Ancylostoma duodenale* and *Necator americanus* (hookworm), *Taenia* spp. (tapeworm) and *Strongyloides stercoralis*.

Albendazole has been shown to be effective in the treatment of *Giardia* (duodenalis or intestinalis or lamblia) infections in children.

CONTRA-INDICATIONS:

Albendazole is known to be teratogenic and embryotoxic in animals. The safety of Albendazole during pregnancy has not been established. Albendazole should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy. Albendazole is contra-indicated in patients with a known history of hypersensitivity to Albendazole or constituents.

DOSAGE AND DIRECTIONS FOR USE:

Usual Dose:

One 400 mg or two Albendazole 200 mg tablets or 20 mL (400 mg) of Albendazole suspension as a single dose in both adults and children over two years of age. The tablets may be chewed, swallowed or crushed and mixed with food. The usual dose in children between one and two years of age is 10 mL (200 mg) of Albendazole suspension as a single dose. In heavy mixed infestation involving *Strongyloides* or *Taeniasis*, a single daily dose may be inadequate and the dose may be given for three consecutive days.

Note:

If the patient is not cured after three weeks, a second course of treatment may be given. No special procedures, such as fasting or purging, are required.

Albendazole has not been adequately studied in children under one year of age.

Giardiasis (dose in children over 2 years of age):

A single 400 mg daily dose for five days.

The tablets may be chewed, swallowed or crushed and they should be taken with food.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported.

Hypersensitivity reactions including rash, pruritus and urticaria have been reported less frequently.

Interactions:

Praziquantel has been reported to increase the plasma levels of the Albendazole active metabolite.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated.

PRESENTATION:

Albendazole 200 mg tablets are available in blister pack strips of two tablets.

Albendazole 400 mg tablets and 400mg chewable tablets are available in jars of 100 tablets

Albendazole suspension is available in 20mL bottles.

STORAGE INSTRUCTIONS:

Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Manufactured by (Tablets)

Emzor Pharmaceutical Industries Ltd
Plot 3C, Block A Aswani Market Road,
Isolo, Lagos

Manufactured by (Suspension)

Emzor Pharmaceutical Industries Ltd
No 10 Kolawole Shonibare Street
Ajao Estate, Isolo, Lagos

Manufactured by (Tablets)

Emzor Pharmaceutical Industries Ltd
No 13, Richfield Avenue, Ajao Estate
Isolo, Lagos