

**PATIENT INFORMATION LEAFLET**  
**[ALDAZ] ALBENDAZOLE TABLETS USP 400 mg**  
**[Albendazole USP]**

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

**WHAT IS IN THIS LEAFLET:**

1. What Albendazole Tablets is and what it is used for
2. Before you use albendazole tablets
3. How to use albendazole tablets
4. Possible side effects
5. How to store albendazole tablets
6. Further information

**1. WHAT ALBENDAZOLE TABLETS IS AND WHAT IT IS USED FOR**

It contain active ingredient albendazole it is a benzimidazole anthelmintic used to treat parenchymal neurocysticercosis and other helminth infections. It is indicated in for single or mixed intestinal infections caused by *Enterobius vermicularis* (Pinworm, Threadworm), *Trichuris trichiura* (Whipworm), *Ascaris lumbricoides* (Roundworm), *Ancylostoma duodenale* & *Necator americanus* (Hookworm), *Taenia solium* & *Taenia saginata* (Tapeworm), *Strongyloides stercoralis*. Also, in giardiasis in children over 2 years of age. Treatment of parenchymal neurocysticercosis caused by cystic hydatid disease of liver, lung & peritoneum caused by *Echinococcus granulosus*.

**2. BEFORE YOU USE ALBENDAZOLE TABLETS**

**Do not take Albendazole Tablets**

If you are allergic (hypersensitive) to {albendazole} or to any of excipients.

If any of the above apply to you.

If you are not sure, talk to your physician, pharmacist or nurse before having albendazole tablets.

**Take special care with Albendazole Tablets**

**Warnings and Precautions:** Talk to your physician before taking albendazole tablets. Use with caution on Albendazole has been noted that leucopenia has occurred when used for periods longer than recommended. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur. Use with caution in patients with hepatic or renal disease. Corticosteroids should be administered before or upon initiation of albendazole therapy to minimize inflammatory reactions and prevent cerebral hypertension.

**Using other medicines:** Tell your physician if you are taking H2 antagonists increase plasma concentrations of albendazole. Praziquantel: Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

**Using Albendazole tablets with food and drink:** It may be taken with or without food or as directed by physician.

**Pregnancy and breast-feeding:**

**Pregnancy:** Pregnancy Category C: it should not be used during pregnancy.

**Lactation:** It is excreted in human milk. Caution should be exercised when albendazole is administered to a nursing woman. Before taking any medicine for advice consult to direction of physician.

**Driving and using machines:** Since dizziness has been reported following treatment with albendazole tablets, caution is recommended in patients performing skilled tasks.

**Important information about some of the ingredients of albendazole tablets** contains each uncoated coated tablet contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

### 3. HOW TO USE ALBENDAZOLE TABLETS

It should be taken as directed by physician. **Method of administration:** For oral use only. It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. **The usual recommended doses: Adults and Children (over two years):** Enterobius vermicularis, Ascaris lumbricoides, Ancylostoma duodenale, Necator americanus and **Trichuris trichiura:** 400 mg as a single dose, taken on an empty stomach. Suspected or confirmed Strongyloides stercora/is infestation: 400mg once daily, taken on an empty stomach for three consecutive days. **Cutaneous larva migrans:** 400 mg once daily, taken with food for one to three days. Suspected or confirmed Taenia spp. or Hymenolepis nana infestation, when other susceptible helminths species are present: 400 mg once daily, taken on an empty stomach for three consecutive days. If the patient is not cured after three weeks, a second course of albendazole treatment is indicated. In cases of proven H. nana infestation, retreatment in 10-21 days is recommended. **Mixed worm infestations including Opisthorchis viverrini and Clonorchis sinensis:** 400 mg twice a day, taken with food for three days is effective.

**If you more Albendazole tablets than you should:** Symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended. **If you forget to albendazole tablets:** If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

### 4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following less adverse effects may have

report. Epigastric pains, diarrhea, headache, nausea, vomiting, dizziness, constipation, purities and dry mouth.

## 5. HOW TO STORE ALBENDAZOLE TABLETS

Keep this medicine out of the sight and reach of children.

Store at temperature not exceeding 30°C, Protect from Moisture.

Do not use Albendazole Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

## 6. FURTHER INFORMATION

**What Albendazole Tablets USP 400 mg Contains:**

**The active substance(s):** Albendazole USP

**Composition:** Each chewable uncoated tablets contain  
Albendazole USP.....400 mg

**The other ingredients are:**

- Maize Starch
- Microcrystalline Cellulose
- Saccharin Sodium
- Povidone
- Sodium Lauryl Sulfate
- Croscarmellose Sodium
- Sodium Starch Glycolate (Type A)
- Colloidal Anhydrous Silica
- Magnesium Stearate
- Orange Flavour
- Tutti-Frutti Flavour
- Colour Sunset Yellow

**What Albendazole Tablets USP 400 mg looks like and contents of the pack**

Light Orange coloured, caplet shaped chewable uncoated tablets having breakline on one side and plain on other side. Pack size: 50 × 1 x 1 Chewable uncoated Tablets packed in Alu-PVC Blister pack.

**Name and full physical address of Marketing Authorization Holder and Manufacturing site:**

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