

PATIENT INFORMATION LEAFLET
ALBENDAZOLE SUSPENSION 200 MG/5ML [ANTHEL]
(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 Suspension 200 mg/5mL is and what it is used for
2. Before you use Albendazole Suspension 200 mg/5mL
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1. WHAT ALBENDAZOLE SUSPENSION 200 MG/5ML IS AND WHAT IT IS USED FOR

It contains active ingredient albendazole. It is a benzimidazole anthelmintic used to treat parenchymal neurocysticercosis and other helminth infections. It is indicated for single or mixed intestinal infections caused by *Enterobius vermicularis* (Pinworm, Threadworm), *Trichuris trichiura* (Whipworm), *Ascaris lumbricoides* (Roundworm), *Ancylostoma duodenale* & *Necator americanus* (Hookworm), *Taenia Saginata* (Tapeworm), infections, when other susceptible helminths species are present. Treatment courses should be extended to 3 days. *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 SUSPENSION 200 MG/5ML

Do not use albendazole suspension 200 mg/5mL. If you are allergic (known hypersensitivity) to albendazole or any of the other ingredients or any other medicines. It should not be administered during pregnancy or in women thought to be pregnant.

Take special care with albendazole suspension 200 mg/5 mL oral suspension: Warnings and Precautions: Talk to your Physician or pharmacist before taking albendazole suspension 200 mg/5 mL oral suspension. **Neurocysticercosis:** For appropriate use of albendazole, corticosteroids should be administered before or upon initiation of albendazole therapy to minimize inflammatory reactions and prevent cerebral hypertension. Anticonvulsant therapy should be used concurrently during the first week of therapy to prevent seizures. It has been noted that leucopenia has occurred when used for periods longer than recommended. It 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. Use of albendazole in patients with impaired renal or hepatic function has not been studied. However, use with caution in patients with pre-existing liver disease, since albendazole is metabolized by liver and has been associated with idiosyncratic hepatotoxicity. Use in Children: It is not recommended in children under 2 years of age due to limited experience. Talk to your Physician or pharmacist if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Taking other medicines: Please tell your Physician, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Cimetidine, praziquantel and dexamethasone have been reported to increase plasma

levels of albendazole active metabolite. Ritonavir, phenytoin, carbamazepine and phenobarbital may have potential to reduce plasma concentrations of albendazole sulfoxide. Clinical relevance of this is unknown, but may result in decreased efficacy, especially in treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies. **Taking albendazole suspension 200 mg/5 mL oral suspension with food and drink:** Patients can take your medicine with or without a meal or as directed by physician. **Pregnancy and breast-feeding:** Ask your physician, health care provider or pharmacist for advice before taking any medicine. **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. **Caution for use:** It contains. **Sucrose:** Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **Liquid Sorbitol:** Patients with hereditary fructose intolerance (HFI) should not take/be given. **Sodium Benzoate:** It may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old). **Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate:** May cause allergic reactions (possibly delayed). **Driving and using machines:** Adverse effects with albendazole suspension 200 mg/5 mL oral suspension on the ability to drive or operate machinery have not been observed.

3. HOW TO USE ALBENDAZOLE SUSPENSION 200 MG/5 ML:

Method of administration: It should be administered orally. Shake well before use. Patient should swallow albendazole suspension 200 mg/5 mL oral suspension. It is best to take your oral suspension at the same time each day. Always use albendazole suspension 200 mg/5 mL oral suspension exactly as your Physician has told you. It should be taken with or without meals or as directed by physician. The dosage schedule of albendazole suspension 200 mg/5 mL oral suspension is mentioned follow: Adults and children over two years: 10 ml suspension (400 mg) as a single dose. **Children (1-2 years):** 5ml suspension (200 mg) as a single dose. **Neurocysticercosis:** Body weight <60 kg: 15 mg/kg/day in 2 divided doses (maximum: 800 mg/day), administered 400 mg (10 ml) twice daily with meals for 8-30 days. Body weight ≥60 kg: 400 mg (10 ml) twice daily with meals for 8-30 days. **Hydatid Disease:** Body weight <60 kg: 15 mg/kg/day in 2 divided doses (maximum: 800 mg/day), administered 400 mg (10 ml) twice daily with meals for 28 days, followed by a 14-day albendazole-free interval. Repeat for a total of 3 dosage cycles. Body weight ≥60 kg: 400 mg (10 ml) twice daily with meals for 28 days, followed by a 14-day albendazole -free interval. Repeat for a total of 3 dosage cycles. **Giardiasis:** A single dose of 400 mg (10 ml) for five days.

If you take more albendazole suspension 200 mg/5 mL oral suspension than you should: If you accidentally take too many albendazole suspension 200 mg/5 mL oral suspension, tell your physician at once or contact your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken. The Symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended.

If you forget to take albendazole suspension 200 mg/5 mL oral suspension: Do not take a double dose to make up for a forgotten dose. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. If any further questions on the use this contact your Physician or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, albendazole suspension 200 mg/5 mL oral suspension can cause side effects, although not everybody gets them. Check with your Physician immediately if any of the following side effects occur: Abdominal pain. Diarrhoea, nausea, vomiting, dizziness, itchiness and/or skin

rashes, bone pain, proteinuria, and low red cell count. Leucopenia and transiently raised hepatic enzymes Hypersensitivity reactions including rash, pruritis and urticaria. During prolonged higher dose albendazole therapy of hydatid disease, reports of severe hepatic abnormalities, including jaundice and hepatocellular damage which may be irreversible if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. HOW TO STORE ALBENDAZOLE SUSPENSION 200 MG/5 ML

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Protect from light. Do not use this medicine 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

It contains: The active substance is albendazole USP. The other ingredient(s) is (are): Xanthan gum BP, Sucrose BP, Liquid sorbitol (Non-Crystallising) BP, Methyl hydroxybenzoate (Methylparaben) BP, Propyl hydroxybenzoate (Propylparaben) BP, Anhydrous citric acid BP, Sodium benzoate BP, Carmellose sodium HVP (Carboxy methylcellulose sodium) BP, Polysorbat-80 (Tween-80) BP, Sodium citrate BP, Ess. Anise, Erythrosine (Supra) Purified water BP. **SHELF LIFE:** 36 months. **Pack:** Albendazole Suspension 200 mg/5 mL Oral Suspension: 10 ml amber PET bottle having 25 mm aluminum cap with LPL logo and 10 ml plastic measuring cup. Such 1 bottle is packed in a printed carton with packing insert.

Manufactured by:

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