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PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Albendazole Chewable Tablets Ph.Int. 400 mg

ALBENDAZOLE CHEWABLE TABLETS 400 MG ARE USED FOR MASS DRUG ADMINISTRATION IN COMMUNITIES AFFECTED BY INTESTINAL WORMS. YOU ARE BEING GIVEN THESE TABLETS UNDER A MASS DRUG ADMINISTRATION PROGRAMME IN WHICH THIS MEDICINE IS ADMINISTERED DEPENDING ON THE RISK OF INFECTION IN YOUR COMMUNITY. MASS DRUG ADMINISTRATION WORKS BY REDUCING THE NUMBER OF PEOPLE IN THE COMMUNITY WHO ARE HEAVILY INFECTED WITH INTESTINAL WORMS.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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2. What you need to know before you take Albendazole Chewable Tablets 400 mg
3. How to take Albendazole Chewable Tablets 400 mg
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6. Contents of the pack and other information

1. WHAT ALBENDAZOLE CHEWABLE TABLETS 400 MG IS AND WHAT IT IS USED FOR

What Albendazole Chewable Tablets 400 mg is
Albendazole Chewable Tablets 400 mg (called Albendazole Tablets in this leaflet) contains the active substance Albendazole belongs to a group of medicines known anthelmintics and antiparasitic, which are effective against certain worms and parasitic in humans.

What Albendazole Tablets is used for

Albendazole Tablets is used to treat hydatid disease which is caused by a worm living inside your body. The inactive worms (larvae) form cysts in the body, which slowly grow bigger. Your medicine kills the larvae, and therefore stops any more cysts growing.

Albendazole Tablets is used for:

- treatment of infections caused by worms, trichinella spiralis, oxides, limbs and tapeworms, tricocephalosis and giardia
- treatment of systemic manifestations caused by parasites, including hydatid disease or neurocysticercosis.

Albendazole Tablets eliminates worms or parasites by affecting their metabolism which determines their death. Both eggs and larvae and adult parasites are affected.

Albendazole chewable tablets 400 mg are used for mass drug administration in communities affected by intestinal worms. You are being given these tablets under a mass drug administration programme in which this medicine is administered depending on the risk of infection

in your community. Mass drug administration works by reducing the number of people in the community who are heavily infected with intestinal worms.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALBENDAZOLE CHEWABLE TABLETS 400 MG.

Do not use Albendazole Tablets:

- if you are allergic (hypersensitive) to albendazole or any of the other ingredients of Albendazole Tablets (see section 6);
- if you know or think you are pregnant or if you intend to become pregnant.

Do not take Albendazole Tablets if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking Albendazole Tablets.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before taking this medicine:

- if you have kidney or liver problems
- if you have had any problems relating to your blood or blood cells
- if you weigh less than 60 kg
- if you are 65 years of age or above

Your doctor will probably carry out regular tests on your liver and blood at the start and during treatment with your medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Albendazole Tablets.

Children and adolescents

Albendazole Tablets is not recommended for children and adolescents weighing less than 60 kg.

In children aged under 6 as there has been limited clinical experience with the use of this medicine in this age group. Although there is clinical experience of older children and adolescents under 60 kg using this medicine, it is not possible to give the correct dose with the 400 mg tablet.

Albendazole Tablets with other medicines

Please tell your doctor, or pharmacist or nurse if you are taking, using or have recently taken or might take/use any other medicines. This is because Albendazole Tablets can affect the way some other medicines work. Also some other medicines can affect the way Albendazole Tablets works.

You must tell your doctor if you are taking the following before taking Albendazole Tablets:

- medicines to treat fits (seizures) and epilepsy, for example phenytoin,
- fosphenytoin, carbamazepine, phenobarbital or primidone
- medicines used to treat worms, for example praziquantel and levamisole
- ritonavir (a medicine used to treat HIV infection)
- cimetidine (a medicine used to treat heartburn and stomach ulcers)
- dexamethazone (a medicine used to reduce inflammation and reduce the effectiveness of your immune system)
- oral contraceptives ("The Pill")
- medicines to thin the blood (anticoagulants)
- medicines to treat diabetes (oral hypoglycaemics)
- theophylline (a medicine used to treat respiratory diseases)

Albendazole Tablets along with food, drink and alcohol

In case of systemic parasitic infections, administer the medicine during the meal.

In the case of intestinal infections and larval cutaneous larvae the drug can be given in during meal time, after meals or on an empty stomach. You should avoid drinking grapefruit juice whilst taking Albendazole Tablets.

Pregnancy, breastfeeding and fertility

Do not take Albendazole Tablets if you are pregnant, think you are pregnant, or are trying to become pregnant. For women of child-bearing age, treatment will only be started after a negative pregnancy test. These tests will be repeated before starting a further course of treatment.

If you are a woman of child-bearing age, you should take precautions against becoming pregnant whilst taking your medicine and for one month after completing the course. You should use a non-hormonal method of contraception, for example condom (sheath), diaphragm or cap with spermicide. "The Pill" should not be used because Albendazole Tablets may affect the way that it works.

It is not known whether the ingredients of Albendazole Tablets can pass into breast-milk. Talk to your doctor about breast-feeding while you are taking Albendazole Tablets. The doctor will weigh-up the benefit to you against any risk to your baby of taking Albendazole Tablets while you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Dizziness is reported as a common reaction. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where this could put them or others at risk.

3 HOW TO TAKE ALBENDAZOLE TABLETS

Albendazole Tablets will be given to you by a health care provider as part of the mass drug administration programme.

Always use this medicine exactly as your doctor or pharmacist has told you.

Talk to your doctor or pharmacist if you are not sure.

Your doctor will recommend how many Albendazole Tablets are needed daily and for how long you must take Albendazole Tablets. The dose depends on your weight or age and the type and severity of infection.

Usual doses

Short-term treatment with low doses

For the treatment of intestinal infections

- with oxy (Oxyurase), limbic (ascariidosis), ankylostomy and non-coriander, tricocephalosis, dose recommended for adults and children over 2 years of age is 1 tablet of Albendazole Tablets administered one only once.
- suspected or diagnosed strongiloidosis, stenosis, hymenolepidosis, the recommended dose in adults, and children over 2 years of age is 1 tablet of Albendazole Tablets per day administered for 3 days consecutive.
- Clonosis, opistorosis, the recommended dose in adults and

- with oxy (Oxyurase), limbic (ascariidiosis), ankylostomy and non-coriander, tricocephalosis, dose recommended for adults and children over 2 years of age is 1 tablet of Albendazole Tablets administered one only once.
- suspected or diagnosed strongiloidosis, stenosis, hymenolepidosis, the recommended dose in adults, and children over 2 years of age is 1 tablet of Albendazole Tablets per day administered for 3 days consecutive.
- Clonrosis, opistorosis, the recommended dose in adults and children over 2 years is 2 Albendazole Tablets daily administered in two doses for 3 consecutive days.
- Dermal migraine larva, the recommended dose in adults and children over 2 years is 1 tablet of Albendazole Tablets daily administered for 1 to 3 days.
- Gardening in children aged 2-12 years, the recommended dose is 1 tablet of Albendazole Tablets per day administered for 5 consecutive days.

Long-term treatment with high doses

For the treatment of systemic infections with

- Cystic echinococcosis (hydatid cyst), alveolar echinococcosis: recommended dose is 800 mg albendazole daily, ie 2 tablets of Albendazole Tablets daily, administered for 28 days.
- Neurocysticercosis: The recommended dose is 800 mg albendazole per day, ie 2 tablets Albendazole Tablets daily given for 7-30 days depending on the response to treatment.
- Capillaries, Gnatostomiasis: The recommended dose is 400 mg albendazole per day, ie 1 tablet of Albendazole Tablets daily, given for 10-20 days.
- Trichinosis, Toxocarose, recommended dose is 800 mg albendazole daily, ie 2 tablets of Albendazole Tablets daily, given for 5-10 days depending on the response to treatment.

Your doctor may find it necessary to examine you 2-3 weeks after you have used the prescribed single dose or after you have completed the treatment cycle to ensure that ALBENDAZOLE TABLETS has had its effect. Sometimes a second or single dose may be required performing a second treatment course.

Children under 6 years:

In children under 6 years of age, albendazole is not recommended for long-term treatment duration with high doses.

For other infections, your doctor may prescribe a different dose of the drug. You must do the treatment in its entirety and you should not stop it if you feel better.

You must follow your doctor's instructions on how and when to use otherwise, you will not benefit from it. It is best to use the same dose of medicine at the same time every day.

If you feel that the effect of Albendazole Tablets is too strong or too weak, please tell your doctor or pharmacist.

How to take

Albendazole Tablets should be taken with meals. Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water, alternatively tablets may be crushed and taken with small amount

of water.

If you take more Albendazole Tablets than you should

You should only take the dose that your doctor or pharmacist has told you to. If you take too many tablets, tell your doctor or hospital casualty department straight away. Show them your pack or container of tablets.

If you forget to take Albendazole Tablets

If you miss a dose, take the next one with your next meal, then take your next dose at the normal time and carry on as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Albendazole Tablets and see a doctor straight away, if you notice any of the serious side effects – you may need urgent medical treatment:

The following are very rare (affects less than 1 in 10,000 people)

a skin reaction known as 'erythema multiforme' where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and private parts. You may have a fever and be very tired

other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches.

Look out for serious symptoms

People being treated for parasite infections may also have a rare and serious condition called neurocysticercosis meaning that they have parasites in the brain. They may not know they have this. By taking Albendazole Tablets a reaction happens in the brain when the parasites are killed. **Tell your doctor immediately** if you get any of the following symptoms:

- headache, which can be severe
- nausea and vomiting
- fits (seizures)
- problems with your vision

Albendazole Tablets can cause uncommon and serious side effects. **You should tell your doctor as soon as possible** if you get any of the symptoms when taking these tablets:
darker urine or paler stools
yellowing of the skin or whites of the eyes

The other possible side effects are:

Very common (may affect more than 1 in 10 people)

- headache
- changes to blood test results, so tell your doctor that you are taking Albendazole Tablets before a blood test.
- Common** (may affect up to 1 in 10 people)
- fever
- dizziness
- upset stomach including feeling sick (nausea), being sick (vomiting) or stomach pain

Thinning of the hair or hair loss, which may happen whilst taking the tablets but returns to normal after.

Uncommon (may affect up to 1 in 100 people)

- liver disease
- blood reaction that causes an increase in infections (like fever, chills, sore throats or mouth ulcers)
- allergic skin reaction causing a rash, itching or hives and rarely it can be severe including flaking, peeling or blistering.

Very rare (may affect up to 1 in 10,000 people)

- blood reactions that cause tiredness, shortness of breath, bruising or bleeding (like nose bleeds) more than normal.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5 HOW TO STORE ALBENDAZOLE TABLETS

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

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.

Do not store above 30°C. Protect from moisture.

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

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Albendazole Tablets contains

The active substance is albendazole. Each tablet contains 400 mg of albendazole.

The other ingredients are Sodium Starch Glycolate, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Maize Starch, Colloidal Anhydrous Silica, Aspartame, Mixed Fruit Flavour, Purified Talc, Magnesium Stearate.

What Albendazole Tablets looks like and contents of the pack

A white to off-white coloured oblong shaped Biconvex, uncoated tablet with breakline on one side and Plain on other Side. A HDPE bottle with CR cap of 1000 tablets.

Marketing authorisation holder and manufacturer



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This leaflet was last revised in: November 2019