

Package leaflet: Information for the patient

Zestaval 200 mg film-coated tablets

albendazole

Read all of this leaflet carefully before you or your child 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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zestaval is and what it is used for
2. What you need to know before you take Zestaval
3. How to take Zestaval
4. Possible side effects
5. How to store Zestaval
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1. What Zestaval is and what it is used for

Zestaval contains the active substance albendazole and it is a medicine (anthelmintic) against worm infestation.

Zestaval is used to treat the following worm infections (helminthoses):

- Dog tapeworm infestation (*Echinococcus granulosus* infection, cystic echinococcosis) both as a preparatory therapy for upcoming surgery or also as therapy for forms of progression for which surgery cannot be performed or for which surgery cannot achieve a complete cure.
- Fox tapeworm infestation (*Echinococcus multilocularis* infection, alveolar echinococcosis) both as a preparatory therapy for upcoming surgery or also as a therapy for forms of progression for which surgery cannot be performed or for which surgery cannot achieve a complete cure.
- Threadworm infestation (*Trichinella spiralis* infection, trichinosis).
- Dwarf nematode infestation (*Strongyloides stercoralis*). Here, a treatment attempt with Zestaval can be made.

2. What you need to know before you take Zestaval

Do not take Zestaval

- if you are allergic to albendazole or to any of the other ingredients of this medicine (listed in section 6).
- in children under 6 years of age, as there is insufficient experience with this group of people.

Zestaval should not be used during pregnancy (see Pregnancy and breast-feeding).

Warning and precautions

Please consult your doctor or pharmacist before taking Zestaval.

- When taking Zestaval, you may temporarily experience a slight to moderate increase in liver enzymes (see section 4 ‘Possible side effects’).
It is therefore important that you keep your appointments with your doctor to check your liver function values. Examinations should be performed before each treatment cycle, after 5 and 10 days and then at 14-day intervals during treatment. If liver enzyme levels increase beyond twice the upper limit of the normal range or if there is a significant change in the blood count, therapy with Zestaval should be discontinued.
Under certain circumstances, therapy with Zestaval can be started again when the liver function values have returned to the values before therapy was started. In this case, however, the liver function values should then be monitored carefully and at shorter intervals (weekly).
- In patients with liver dysfunction: Patients who show abnormal levels of liver enzymes before starting treatment with Zestaval should be carefully monitored and therapy discontinued if enzyme levels are significantly elevated.
- There may be a temporary reduction in blood cells when Zestaval is used (see section 4 ‘Possible side effects’). You should therefore make sure that the blood values (number of blood cells) are also determined at the dates when the liver values are to be checked.
- Consult your doctor before you give Zestaval in elderly patients with renal dysfunction.
- In patients treated with albendazole, a pre-existing infection of the brain (neurocysticercosis) may become apparent, especially in areas with pronounced taeniasis infection. These patients may experience neurological symptoms, such as seizures, increased intracranial pressure or specific neurological symptoms that are the result of an inflammatory reaction triggered by the parasites dying in the brain. Symptoms may appear shortly after treatment. Appropriate therapy with corticosteroids and anticonvulsants (drugs used to treat seizures) should be started immediately.

Children and adolescents

Zestaval is contraindicated in children under 6 years old.

Other medicines and Zestaval

Inform your doctor or pharmacist if you are taking/using, have recently taken/used or intend to take/use any other medicines, including medicines that are not subject to prescription.

The simultaneous administration of Zestaval with cimetidine (stomach acid blocker), praziquantel (anthelmithic agent) or dexamethasone (anti-inflammatory agent) may cause the active ingredient of Zestaval to accumulate in the blood. Please inform your doctor if you are taking or have recently taken any of these medicines.

Ritonavir (for the treatment of HIV infection), phenytoin, carbamazepine and phenobarbital (for the treatment of seizures (epileptic seizures) and epilepsy) may possibly reduce the plasma concentrations of the active metabolite of albendazole, albendazole sulphoxide. The significance for disease progression is not known, but there could be reduced efficacy, especially in the treatment of systemic worm infections (helminthoses).

Zestaval with food, drink and alcohol

The absorption of Zestaval into the body can be increased by fatty foods, so you should make sure that your meals are composed accordingly. If possible, consume the fat in solid (not liquid) form and make sure that the fat content per meal is above 40 g (see section 3 'Method of administration').

Pregnancy and breast-feeding

If you are pregnant or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

There are no suitable data from the use of albendazole in pregnant women. Data from animal studies have shown that it can affect fertility and damage the fetus in the womb. The possible risk to humans is not known.

Albendazole should not be taken during pregnancy unless clearly necessary.

To exclude pregnancy, a test should be carried out in women of childbearing age before starting and regularly during treatment with Zestaval. If you are of childbearing age, you should definitely use effective contraception during therapy. Start contraceptive measures shortly before therapy and continue them until 1 month after the end of therapy. Please use other means (e.g. diaphragm, condom) besides hormonal contraception ("the pill"), as the effect of the "pill" may be impaired by taking Zestaval.

You should take a pregnancy test both before starting the treatment and before starting each of the following treatment cycles.

Zestaval should not be used during breast-feeding as there are insufficient data in breast-feeding women or from animal studies.

Driving and using machines

According to previous experience, albendazole has no effect on the ability to concentrate and react.

Zestaval contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

Zestaval contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zestaval

Always take this medicine exactly as advised by your doctor. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Dosage

Dog or fox tapeworm infestation

If you are given Zestaval to treat a dog or fox tapeworm infestation, you should take 2 tablets of Zestaval (400 mg) 2 times a day for 28 days. Then stop the treatment for 14 days before taking 2 tablets 2 times a day for another 28 days. After a further break, a third treatment cycle of 28 days can be added if necessary.

In preparation for surgery (pre-operative):

If you are going to have a surgery because of a disease, two 28-day treatments according to the above schedule should be carried out before the operation, if possible. If surgery is to be performed before the two treatment cycles are completed, Zestaval should be given as long as possible beforehand. However, you should not take Zestaval for more than 28 days in a row.

Follow-up treatment in case of early surgery (post-operative):

If you have surgery less than 14 days after starting treatment, Zestaval should be taken 2 times for 28 days after surgery with a 14-day break (as described above). Even if cysts (sac-like growths) are still present before the surgery or if they rupture during the surgery, this regimen should be followed.

People with a body weight of less than 60 kg receive 15 mg of active substance per kg of body weight per day, divided into 2 doses. The maximum dose is 800 mg/day.

Threadworm infestation

To treat threadworm infestation (trichinosis), take 2 tablets (400 mg) 2 times a day for 6 days. Normally, no repeated treatment is necessary.

Dwarf threadworm infestation

In the case of a confirmed diagnosis or suspected nematode infestation, take 2 tablets (400 mg) once a day for 3 consecutive days.

Elderly

Experience with elderly patients (65 years and older) is limited. Reports indicate that no dosage adjustment is necessary.

Renal impairment

As the renal excretion of albendazole and its primary metabolite albendazole sulphoxide is negligible, no dosage adjustment is required.

Hepatic impairment

In patients with hepatic dysfunction, the warnings should be followed (see 'Warnings and precautions').

Method of administration

Oral use.

Zestaval should be taken with meals (in the morning or morning and evening, depending on the dosage), preferably with some liquid. The absorption of Zestaval into the body can be increased by fatty foods, so you should make sure that your meals are composed accordingly. If possible, consume fat in solid (not liquid) form and make sure that the fat content per meal is above 40 g.

Duration of the treatment

The duration of treatment varies depending on what type of worm infestation you are receiving Zestaval for (see 'Dosage').

If you take more Zestaval than you should

Consult your doctor immediately. Albendazole is not acutely harmful even in high doses. Nevertheless, you are more likely to experience side effects if you have taken an excessive dose of Zestaval. Therefore, in this case your liver and blood values should be checked. Further treatments should be given according to clinical presentation or as recommended.

If you forget to take Zestaval

Please take it as soon as possible. Then take the next tablet again at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zestaval

The success of the treatment may be compromised. Therefore, you should follow the doctor's instructions exactly.

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

4. Possible side effects

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

The following side effects have been observed so far:

Very common: may affect more than 1 in 10 people

- Headache.
- Slightly to moderately elevated liver enzyme levels.

Common: may affect up to 1 in 100 people

- Dizziness
- Abdominal pain.
- Diarrhoea.
- Nausea.
- Vomiting.
- Reversible hair loss (thinning of the hair, moderate hair loss).
- Fever.

Uncommon: may affect up to 1 in 1,000 people

- Decrease of the white blood cells (leukopenia).
- Allergic reactions (hypersensitivity reactions) including skin rash, itching and hives (urticaria).
- Worsening of existing symptoms during treatment of a worm infestation of the nervous system (neurocysticercosis).
- Seizures.
- Meningitis.
- Hemiplegia.
- Noticeable fatigue.
- Liver inflammation (hepatitis).
- Results deviating from the norm in liver tissue examinations (liver biopsy) have also been reported. However, these were probably a consequence of the worm infestation.
- Nosebleed.

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

- Decrease in a certain subgroup of white blood cells (agranulocytosis).
- Decrease of all blood cells (pancytopenia).
- Decrease in red blood cells (aplastic anaemia).

- Life-threatening general reactions with extensive blistering of the skin (erythema multiforme, Steven-Johnson syndrome).

Patients with liver disease, including hepatic echinococcosis, appear to be more susceptible to bone marrow cell reduction (see section 2 ‘Warning and precautions’ and section 3 ‘How to take Zestaval’).

In case of symptoms of poisoning/overdose, further treatment should be given depending on the clinical presentation or as recommended by poisoning information centers.

Since side effects must be expected as a consequence of poisoning, checking the blood count and liver values is recommended.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zestaval

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 carton after “EXP”. The expiry date refers to the last day of that month.

Store below 25 °C. Protect from light and moisture.

6. Contents of the pack and other information

What Zestaval contains

- The active substance is albendazole. Each film-coated tablet contains 200 mg of albendazole.
- The other ingredients are lactose, maize starch, povidone, microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, talc, hypromellose, polyethylene glycol 400, titanium dioxide E171.
See section 2 ‘Zestaval contains lactose and sodium’.

What Zestaval looks like and the contents of the pack

White, round, film-coated tablets with star embossed on both sides.

Pack sizes:

Cardboard box containing Aluminium-PVC blister, of 2 film-coated tablets.

Pack size of 2 film-coated tablets.

Marketing Authorization Holder and Manufacturer

Remedica Ltd

Aharnon Str., Limassol Industrial Estate,

3056 Limassol, Cyprus

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For internal use only: am-pl-zestaval-200mg-fc-tabs-a0