APPROVED
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INSTRUCTION
for medical use

ALBELA®

Composition:
active substance: albendazole;
1 tablet contains albendazole 400 mg;
excipients: lactose monohydrate, corn starch, sodium lauryl sulfate, sodium croscarmellose, povidone, microcrystalline cellulose, saccharin sodium, magnesium stearate, colloidal anhydrous silica, flavor "Orange".

Pharmaceutical form. Tablets.
Basic physical and chemical properties: white or almost white, capsule-shaped, biconvex tablets with specific odor, smooth on both sides.

Pharmacotherapeutic group.
Anthelmintic drugs. Antinematodal agents. Benzimidazole derivatives.
ATC code P02C A03.

Pharmacological properties.
Pharmacodynamics.
Albendazole is an antiprotozoal and anthelmintic drug of the group of benzimidazole carbamate. The drug acts both on the intestinal and tissue parasites in the form of eggs, larvae and adult forms of helminths. Anthelmintic effect of albendazole is due to inhibition of tubulin polymerization, which leads to metabolic disorders and death of helminths.
Albendazole acts against such intestinal parasites as: nematodes – *Ascaris lumbricoides, Trichuris trichiura, Enterobius vermicularis, Ancylostoma duodenale, Necator americanus, Strongyloides stercoralis, Cutaneus Larva Migrans*; cestodes – *Hymenolepsis nana, Taenia solium, Taenia saginata*; trematodes – *Opisthorchis viverrini, Clonorchis sinensis*; protozoa – *Giardia lamblia (intestinalis or duodenalis)*.
Albendazole acts against tissue parasites, including cystic and alveolar echinococcosis caused by invasion of *Echinococcosus granulosus* and *Echinococcosus multilocularis* respectively. Albendazole is an effective treatment for neurocysticercosis, larval infestation of *Taenia solium,* capillariasis, caused by *Capillaria philippinensis,* and gnathostomosis, caused by invasion of *Gnathostoma spinigerum.*
Albendazole eliminates cysts or significantly reduces their size (up to 80%) in patients with granular echinococcosis. After treatment with albendazole, the number of non-viable cysts increases to 90% compared to 10% in patients who did not receive the treatment. After using albendazole for treatment of cysts caused by *Echinococcus multilocularis,* complete recovery was observed in minority of patients, while the majority experienced improvement or stabilization of condition.
Pharmacokinetics.
In oral administration albendazole is poorly absorbed (less than 5%). The systemic effect increases if the dose of the drug is taken with fatty food, which 5 times increases the absorption of the drug. It is rapidly metabolized in the liver during its first passage. The main metabolite is albendazole sulphate, which is the main effective substance for treatment of tissue infections. The half-life period is 8.5 hours. Albendazole sulphate and its metabolites are excreted mostly with the bile, and only minor part is excreted with the

urine. It is known that when prolonged administration of high doses of the drug its elimination from cysts lasts for several weeks.
Elderly patients.
Some clinical data suggest that pharmacokinetics in elderly patients is similar to the one in young healthy volunteers.
Renal failure.
Pharmacokinetics of albendazole has not been studied in this group of patients.
Hepatic failure.
Pharmacokinetics of albendazole has not been studied in this group of patients.

Clinical characteristics.
Indications.
Intestinal forms of helminth infestation and cutaneous *Larva Migrans* (short-term treatment with low doses): enterobiasis, ankylostomiasis and necatoriasis, hymenolepiasis, teniasis, strongyloidosis, ascariasis, trichocephaliasis, clonorchiasis, opisthorchiasis, cutaneous *Larva Migrans*, lambliasis in children.
Systemic helminth infections (long-term treatment with high doses):
cystic echinococcosis (caused by *Echinococcus granulosus*):
- when surgery is impossible;
- before surgery;
- after surgery, if presurgical treatment was short, if dissemination of helminths is observed, or living forms have been found during the surgery;
- after percutaneous drainage of cysts for diagnostic or therapeutic purposes;

alveolar echinococcosis (caused by *Echinococcus multiocularis)*:
- when the disease is inoperable, particularly in case of local or distant metastases;
- after palliative surgery;
- after radical surgery or liver transplantation;

neurocysticercosis (caused by larvae of *Taenia solium*):
- in presence of isolated or multiple cysts or granulomatous brain lesion;
- in case of arachnoidal or intraventricular cysts;
- in racemous cysts;

capillariasis (caused by *Capillaria philippinensis*), gnathostomosis (caused by *Gnathostoma spinigerum* and related species), trichinellosis (caused by *Trichinella spiralis* and *T.pseudospiralis*), toxocariasis (caused by *Toxocara canis* and related species).

Contraindications.
Hypersensitivity to albendazole or any other component of the drug.
Pregnancy or breast feeding.
Women that are planning to conceive. Women of reproductive age should use effective non-hormonal contraception during and 1 month after the drug treatment.

Interaction with other medicinal products and other forms of interaction.
Albendazole induces enzymes of the system of cytochrome P450.
Medicinal products that can insignificantly reduce the efficacy of albendazole: anticonvulsants (e.g., phenytoin, fosphenytoin, carbamazepine, phenobarbital, primidone), levamisole, ritonavir. The efficacy of treatment of patients should be controlled and if necessary, alternative dosage regimens or therapy should be used.
Cimetidine, praziquantel and dexamethasone increase plasma levels of metabolite of albendazole, which is responsible for systemic activity of the drug, which in turn can lead to the growth of the frequency of adverse reactions.
Grapefruit juice also increases the plasma level of albendazole sulfoxide.
Because of the possible violation of cytochrome P450 activity, there is a theoretical risk of interaction of albendazole with such medicinal products: oral contraceptives, anticoagulants, oral hypoglycemic agents, theophylline.

Administration details.

Treatment of intestinal forms of helminths and cutaneous Larva Migrans.
To prevent using the drug Albela® during early pregnancy, women of reproductive age should be treated during the first week of menstruation or after a negative pregnancy test. During treatment with albendazole and within month after its discontinuation, reliable contraception is necessary.
Treatment with albendazole may reveal the present neurocysticercosis, especially in the territories with high level of infestation with strains *Tenia solium*. The patients may have neurological symptoms, e.g., convulsions, increased intracranial blood pressure and focal symptoms due to the inflammatory reaction caused by death of parasites in the brain. The symptoms may occur soon after treatment, therefore, appropriate therapy with corticosteroids and anticonvulsants should be started as soon as possible.
Treatment of systemic helminth infections.
Treatment with albendazole is accompanied with mild to moderate increase in the level of liver enzymes that usually returns to normal after discontinuation of treatment. Cases of hepatitis have been reported. Therefore, the level of liver transaminases should be checked before each treatment course and at least every 2 weeks during treatment. If the level of liver transaminases has significantly increased (more than 2-fold compared to the upper limit of normal), the treatment with albendazole should be stopped. The treatment may be resumed after normalization of the level of enzymes, but the patient's condition should be closely monitored.
Albendazole may cause bone marrow suppression; therefore, blood tests should be carried out both at the start of treatment and every 2 weeks during the 28-day cycle. Patients with the liver disease, including liver echinococcosis are more likely to have bone marrow suppression, which results in pancytopenia, aplastic anemia, agranulocytosis and leukemia which causes the necessity of thorough control of blood parameters. In case of significant worsening of the blood parameters, the treatment should be stopped (see sections "Dosage and administration" and "Adverse reactions").
To prevent using Albela® in the early stages of pregnancy, women of childbearing age should:
- start treatment only after a negative pregnancy test
- warn about the need to use effective contraception during treatment and within a month after its cancellation.
Patients with neurocysticercosis that are treated with albendazole may have symptoms associated with inflammatory reaction caused by death of parasites (e.g., convulsions, increased intracranial blood pressure and focal symptoms). Such adverse reactions should be treated with corticosteroids and anticonvulsive drugs. To prevent the cases of increase of intracranial pressure during the first week of treatment, it is recommended to use oral or intravenous corticosteroids.
Albendazole treatment may also reveal pre-existing neurocysticercosis, especially in areas with high rates of *Taenia solium* infection. Neurological symptoms such as seizures, increased intracranial pressure, and focal symptoms may occur in patients due to an inflammatory response caused by the death of parasites in the brain. Symptoms may occur quickly after treatment, so appropriate therapy with corticosteroids and anticonvulsants should be initiated immediately.
Excipients. The drug contains lactose. If a patient has a history of intolerance to some sugars, he should consult a doctor before using this medicinal product.

Use during pregnancy or breast feeding.
The drug is contraindicates for use during pregnancy or breast feeding and for treatment of women planning to conceive (see section "Contraindications").

Effect on reaction rate when driving motor transport or using other mechanisms.
Taking into account the presence of such adverse reaction as dizziness, for the period of using albendazole, it is recommended to refrain from driving motor transport or working with other mechanisms.

Dosage and administration.
Intestinal infections and cutaneous Larva Migrans.
The drug should be taken with food. It is preferable to use the drug at the same hour of the day. If no recovery occurs within 3 weeks, the doctor should prescribe the second course of treatment.
Some patients, especially children, may have difficulty when swallowing the whole tablet. In such case the tablet may be chewed with a small amount of water, or it can be crushed.
Use in adults and children aged 3 years and older.

Infection	Patient's age	Doses and duration of treatment
Enterobiasis, ankylostomiasis, necatoriasis, ascariasis, trichocephaliasis	Adults and children aged 3 years and older*	400 mg (1 tablet) 1 time/day, single dose.
Strongyloidosis, teniasis, hymenolepiasis	Adults and children aged 3 years and older*	400 mg (1 tablet) 1 time/day for 3 days. In hymenolepiasis, a repeated course of treatment is recommended with an interval of 10 to 21 days after the previous course.
Clonorchiasis, opisthorchiasis	Adults and children aged 3 years and older*	400 mg (1 tablet) 2 times/day for 3 days.
Cutaneous *Larva Migrans*	Adults and children aged 3 years and older*	400 mg (1 tablet) 1 time/day for 1-3 days.
Lambliasis	Only children aged 3 to 12 years*	400 mg (1 tablet) 1 time/day for 5 days.

* For children aged 2 to 3 years, albendazole preparation should be used in appropriate dosage.

Elderly patients.
The experience of using the drug for treatment of elderly persons is limited. Dosage adjustment is not required; however, albendazole should be used with caution for treatment of elderly patients with hepatic impairment.
Renal failure.
Since albendazole is excreted by the kidneys in a very insignificant amount, dosage adjustment for treatment of this category of patients is not required; however, in the presence of signs of renal failure, such patients should be under close supervision.
Hepatic failure.
Since albendazole is actively metabolized in the liver to pharmacologically active metabolite, hepatic dysfunction may have significant effect on its pharmacokinetics. Therefore, patients with changed liver function parameters (increased level of transaminases) at the beginning of using albendazole should be under close supervision.
Systemic helminth infections (long-term treatment with high doses).
The drug should be taken with meal.
Use in adults and children aged 6 years and older.
Administration of high doses of the drug in children less than 6 years of age is not recommended. The dosage regimen is set by the doctor individually depending on the age, body weight and severity of the infection.
The dose for patients with body weight more than 60 kg is 400 mg (1 tablet) 2 times per day. With body weight less than 60 kg the drug is administered at a dose of 15 mg/kg/day. This dose should be divided into 2 doses. The maximum daily dose is 800 mg.

Infection	Duration of treatment
Cystic echinococcosis	28 days. The 28-days' cycle may be administered repeatedly (3 times in total) after an interval of 14 days.

Infection	Duration of treatment
- Inoperable and multiple cysts	Up to three 28-days' cycles for the treatment of hepatic, pulmonary and peritoneal cysts. In the presence of cysts of other localization (in the bones or brain) a longer treatment may be required.
- Before surgery	Before surgery, two 28-days' cycles are recommended. If the surgery is to be performed before these cycles are completed, the treatment should be continued as long as possible before the start of the surgery.
- After surgery - After percutaneous drainage of cysts	If before surgery a short (less than 14 days) course of treatment was given or if urgent surgery was performed, after the surgery two 28-days' cycles of administering the drug should be performed with a 14-days' interval. Similarly, if viable cysts have been found or dissemination of helminths occurred, two complete cycles of treatment should be conducted.
Alveolar echinococcosis	28 days. The second 28-days' course should be repeated after a two-weeks' interval in using the drug. The treatment may be prolonged for several months or years.
Neurocysticercosis**	Duration of treatment is from 7 to 30 days. The second course may be taken after a two-weeks' interval in using the drug.
- Cysts in the parenchyma and granulomas	The usual treatment duration is from 7 days (minimum) to 28 days.
- Arachnoidal and intraventricular cysts	The normal course is 28 days.
- Racemous cysts	The normal treatment course is 28 days, but it may last longer. The treatment duration is determined by clinical and radiological response to treatment.

** In treatment of patients with neurocysticercosis, appropriate corticosteroid and anticonvulsant therapy should be administered. Oral and intravenous corticosteroids are recommended for the prevention of intracranial hypertension during the first week of treatment.

Infection	Dose and duration of treatment
Capillariasis	400 mg 1 time per day for 10 days***.
Gnathostomosis	400 mg 1 time per day for 10-20 days***.
Trichinellosis, toxocariasis	400 mg 2 times per day for 5-10 days***.

***Usually, one course of treatment is necessary, but additional courses may be required if the results of parasitological examination remain positive.

Elderly patients.
The experience of using the drug for the treatment of elderly persons is limited. Dosage adjustment is not required; however, albendazole should be used with caution for the treatment of elderly patients with hepatic impairment.
Renal failure.
Since albendazole is excreted by the kidneys in a very insignificant amount, dosage adjustment for the treatment of this category of patients is not required; however, in the presence of signs of renal failure, such patients should be under close supervision.
Hepatic failure.
Since albendazole is actively metabolized in the liver to pharmacologically active metabolite, hepatic dysfunction may have significant effect on its pharmacokinetics. Therefore, patients with changed liver function parameters (increased level of transaminases) at the beginning of using albendazole should be closely examined. In case of a significant increase in the level of transaminases or a clinically significant worsening of blood parameters, the treatment should be stopped (see sections "Administration details" and "Adverse reactions").

Children.
The drug is intended for use in children aged 3 years and older. Children aged 2 to 3 years should be treated using a different pharmaceutical form – oral suspension.
The drug should be used in children according to the information provided in section "Dosage and administration".

Overdose.
Symptoms. Depending on the ingested drug dose, in case of overdose, diarrhea, nausea, vomiting, tachycardia, increase in transaminase levels may occur.
Treatment: symptomatic, according to the clinical condition.

Adverse reactions.
Adverse reactions associated with short-term treatment of intestinal infections and the *Larva Migrans* skin syndrome.
Immune system: hypersensitivity reactions, including rash, itching and urticaria.
Nervous system: headache, dizziness.
Gastrointestinal tract: symptoms in the upper gastrointestinal tract (e.g., epigastric pain, nausea, vomiting), diarrhea.
Hepatobiliary system: increase in liver enzymes.
Skin and subcutaneous tissue: erythema multiforme, Stevens-Johnson syndrome.
Adverse reactions associated with long-term treatment of systemic helminth infections.
Blood and lymphatic system: leukopenia, pancytopenia, aplastic anemia, agranulocytosis.
Patients with liver diseases, including hepatic echinococcosis, are more likely to have bone marrow suppression (see sections "Dosage and administration" and "Administration details").
Immune system: hypersensitivity reactions, including rash, itching and urticaria.
Nervous system: headache, dizziness.
Gastrointestinal tract: symptoms in the upper gastrointestinal tract (e.g., epigastric pain, nausea, vomiting), diarrhea. These phenomena are associated with the treatment of patients with echinococcosis using albendazole.
Hepatobiliary system: mild to moderate increase in liver enzymes, hepatitis.
Skin and subcutaneous tissue: erythema multiforme, Stevens-Johnson syndrome, alopecia (thinning of hair and moderate hair loss).
General disorders: fever.

Shelf life. 3 years.

Storage conditions.
Store in the original package at a temperature not more than 25 °C.
Keep out of reach of children.

Package.
1 tablet is in a blister; 1 or 3 blisters are in a carton package.
3 tablets are in a blister; 1 blister is in a carton package.

Condition of supply.
Prescription only.

Manufacturer.
LLC "KUSUM PHARM".

Address of manufacturer and manufacturing site.
40020, Ukraine, Sumy region, Sumy, Skryabina Str., 54.

or

Manufacturer.
LLC “GLADPHARM LLC”.

Address of manufacturer and manufacturing site.
40020, Ukraine, Sumy region, Sumy, Davydovskoho Hryhoriia Str., 54.

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12.06.2025