

Potassium Orotate®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Orotate Acid

DOSAGE FORM AND STRUCTURE:

Active ingredient: potassium orotate – 500.0 mg.

Excipients: lactose monohydrate– 165.0 mg, potato starch–55.0 mg, povidone K-17 - 22.5 mg, calcium stearate - 7.5 mg.

DESCRIPTION: Round flat cylindrical tablets of white color with a facet and a break line on one side. 20 pcs per pack

PHARMACOLOGICAL GROUP: metabolic agent

ATC CODE: A05BA Liver therapy

PHARMACOLOGICAL CLASSIFICATION:

Nosological classification (ICD-10):

- D64 Other anaemias;
- E46 Unspecified protein-energy malnutrition;
- I42 Cardiomyopathy;
- K71 Toxic liver disease;
- K73 Chronic hepatitis, not elsewhere classified;
- R53 Malaise and fatigue.

PHARMACOLOGICAL ACTION: diuretic, anabolic.

PHARMACODYNAMICS:

The medication is a potassium salt of orotic acid. Orotic acid is one of the precursors of the pyrimidine nucleotides that make up the nucleic acids that are involved in the synthesis of protein molecules. Thus salts of orotic acid are considered substances of anabolic action and are used to treat protein metabolism disorders and to stimulate it. Potassium Orotate® stimulates the synthesis of nucleic acids and the generation of albumin in the liver, especially in case of prolonged hypoxia (oxygen deficiency); it increases the appetite, has diuretic and regenerative properties.

PHARMACOKINETICS:

After an oral administration, 10% of the dose is absorbed in the gastrointestinal tract. In the liver, it is converted into orotidine-5-phosphate. Excreted by the kidneys (30% in the form of metabolites).

INTENDED USES:

- As an adjuvant in the complex therapy: diseases of the liver and the bile ducts caused by acute and chronic intoxications (with the exception of organic lesions of the liver and the bile ducts);
- Consequences of malnutrition in children (alimentary and alimentary-infectious hypotrophy);
- During the recovery period after an illness;
- In case of chronic physical overexertion.

CONTRAINDICATIONS:

- Hypersensitivity to the drug components;
- Acute and chronic organic liver damage (including cirrhosis);

- Ascites (fluid accumulation in the abdominal cavity);
- Urolithic disease;
- Renal failure;
- Children under 3 years old.

DOSAGE AND ADMINISTRATION:

The medication should be taken orally 1 hour before a meal or 4 hours after a meal.

Adults - 250–500 mg 2-3 times a day. The course of treatment lasts for an average of 20-30 days. If necessary, the treatment can be repeated after 1 month. In exceptional cases, you can increase the adult dose up to 3 g per day.

Children - 10-20 mg/dose per day, divided into 3-4 doses (for example, if the child's body weight is 25 kg, then the permitted dose is from $25 \times 10 = 250$ mg (1/2 tablet) to $25 \times 20 = 500$ mg (1 tablet) per day, divided into 3-4 doses). The course of treatment is 3-5 weeks.

If symptoms persist, consult a doctor.

PRECAUTION:

During the treatment period the diet is desirable.

SIDE EFFECTS:

Usually Potassium Orotate® is well tolerated. In some cases, allergic skin reactions may occur. They disappear after an interruption of the treatment. Potassium Orotate® can also cause mild indigestion (nausea, vomiting, and diarrhea). When used in high doses with a low-protein diet, liver dystrophy may develop.

If side effects occur, consult your doctor.

OVERDOSE:

There are no data on overdose.

INTERACTION WITH OTHER DRUGS:

Astringents and enveloping agents may slightly reduce the absorption of Potassium Orotate® in the gastrointestinal tract. The absorption of iron, tetracycline and sodium fluoride is affected (the interval between the intake of drugs is at least 2-3 hours). Oral contraceptives, diuretics, muscle relaxants, glucocorticoid drugs and insulin reduce the effect of the medication.

PREGNANCY AND LACTATION:

With caution.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE

MECHANISMS:

The medication does not cause drowsiness or reduce the speed of psychomotor reactions.

STORAGE CONDITIONS:

Store in a dry place, at a temperature not exceeding 25 ° C. Keep out of the reach of children.

SHELF LIFE:

4 years. Do not use beyond the expiration date.

MANUFACTURER: JSC PFK Obnovleniye, Russia.