Isoprinosine®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Inosinum pranobexum.

DOSAGE FORM AND STRUCTURE:
Active ingredient: inosine pranobex (Isoprinosine) 500 mg;
Excipients: mannitol, wheat starch, povidone, magnesium stearate.

DESCRIPTION: Oblong biconvex tablets of white or almost white color with a slight amine odor, and a break line on one side.

ATC CODE: J05AX05 Inosine pranobex.

PHARMACOLOGICAL ACTION: Immunostimulating, antiviral.

PHARMACODYNAMICS:

Isoprinosine is a synthetic complex derivative of purine with immunostimulating activity and a non-specific antiviral effect. It restores the functions of lymphocytes under immunosuppression, increases blastogenesis in the population of monocytic cells, stimulates the expression of membrane receptors on the surface of T-helpers, prevents the decrease in the activity of lymphocyte cells under the influence of glucocorticosteroids, and normalizes the incorporation of thymidine into them. Isoprinosine exhibits a stimulating effect on the activity of cytotoxic T-lymphocytes and natural killers, and on the function of T-suppressors and T-helpers. It increases the production of immunoglobulin (lg) G, interferon-gamma, interleukins (IL)-1 and IL-2, reduces the formation of pro-inflammatory cytokines - IL-4 and IL-10, and potentiates chemotaxis of neutrophils, monocytes and macrophages. The drug exhibits antiviral activity in vivo against Herpes simplex viruses, cytomegalovirus and measles virus, type III human T-cell lymphoma virus, polioviruses, influenza A and B, ECHO virus (Enteric Cytopathic Human Orphan), encephalomyocarditis and equine encephalitis. The mechanism of the antiviral effect of Isoprinosine is associated with the inhibition of viral RNA and the dihydropteroate synthetase enzyme, which is involved in the replication of certain viruses; it enhances the synthesis of mRNA lymphocytes suppressed by viruses, which is accompanied by a suppression of the biosynthesis of viral RNA and the translation of viral proteins, and increases the production of lymphocytes with antiviral properties of interferons-alpha and gamma. In a combined treatment, it enhances the effect of interferon-alpha, antiviral agents acyclovir and zidovudine.

PHARMACOKINETICS:
After an oral administration, the drug is well absorbed from the gastrointestinal tract. The maximum concentration of ingredients in blood plasma is determined after 1-2 hours. It is rapidly metabolized and excreted through the kidneys. It is metabolized similarly to endogenous purine nucleotides with the formation of uric acid. N-N-dimethylamino-2-propranolone is metabolized to N-oxide, and para-acetamidobenzoate - to o-acyl glucuronide. Cumulation of the drug in the body is not detected. The half-life is 3.5 hours for N-N-dimethylamino-2-propranolone and 50 minutes for para-acetamidobenzoate. Elimination of the drug and its metabolites from the body occurs within 24-48 hours.

INTENDED USES:
- ✓ Treatment of influenza and other acute respiratory viral infections;

- ✓ Infections caused by Herpes simplex virus of the 1st, 2nd, 3rd and 4th types: genital and labial herpes, herpetic keratitis, herpes zoster, chickenpox, infectious mononucleosis caused by the Epstein-Barr virus;
- ✓ Cytomegalovirus infection;
- ✓ Severe measles;
- ✓ Papillomavirus infection: papilloma of the larynx / vocal cords (fibrous type), papillomavirus infection of the genitals in men and women, warts;
- ✓ Molluscum contagiosum.

CONTRAINDICATIONS:

- Hypersensitivity to the drug components;
- Gout;
- Kidney stone disease;
- Arrhythmia;
- Chronic renal failure;
- Children under 3 years old (body weight up to 15-20 kg).

PRECAUTION:

After 2 weeks of using Isoprinosine, a concentration of uric acid in the blood serum and urine should be monitored. It is advisable to monitor liver and kidney functions (plasma transaminase activity, creatinine, uric acid) every month after a 4-week use, in case of the long-term application. It is necessary to control the level of uric acid in the blood serum when using Isoprinosine in combination with drugs that increase the level of uric acid or drugs that impair renal function.

DOSAGE AND ADMINISTRATION:

The tablets are taken orally after a meal with some water.
The recommended dose for adults and children from 3 years old (body weight over 15-20 kg) is 50 mg / kg per day, divided into 3-4 intakes. For adults - 6-8 tablets per day, for children - ½ of the tablet per 5 kg / body weight per day. In severe forms of infectious diseases, the dose can be individually increased up to 100 mg / kg body weight per day, divided into 4-6 intakes. The maximum daily dose for adults is 3-4 g / day, for children - 50 mg / kg / day.
Duration of treatment:

- *Acute diseases:* the duration of treatment in adults and children usually lasts from 5 to 14 days. The treatment should be continued until the disappearance of clinical symptoms and for another 2 days in the absence of the symptoms. If necessary, the duration of treatment can be increased individually under the supervision of a physician.
- *In case of chronic recurring diseases* in adults and children, the treatment should be continued with several courses of 5-10 days with a break in admission of 8 days. In the maintenance therapy, the dose can be reduced to 500-1000 mg per day (1-2 tablets) for 30 days.
- *In case of a herpetic infection,* the drug is prescribed for adults and children for 5-10 days until the symptoms disappear; in the asymptomatic period, 1 tablet 2 times a day for 30 days is prescribed to reduce the number of relapses.
- *In human papillomavirus infection*, adults are prescribed 2 tablets 3 times a day, children - ½ of a tablet per 5 kg / body weight per day in 3-4 intakes for 14-28 days as a monotherapy.
- *In relapsing genital condylomata acuminata,* adults are prescribed 2 tablets 3 times a day, and children - ½ tablet per 5 kg / body weight per day divided into 3-4 intakes per day, either as a monotherapy or in a combination with a surgical treatment for 14-28 days, then the course is repeated three times with 1-month intervals.

- *In cervical intraepithelial neoplasia associated with the human papilloma virus*, 2 tablets are prescribed 3 times a day for 10 days, and then the course is repeated 2-3 times with an interval of 10-14 days.

SIDE EFFECTS:
The incidence of side effects after using the drug is classified according to WHO recommendations.
Often: ≥1% and <10%.
Sometimes: ≥0.1% and <1%.
On the part of the gastrointestinal tract: often - nausea, vomiting, epigastric pain; sometimes - diarrhea, constipation.
On the part of the liver and biliary tract: often - a temporary increase in the activity of transaminases and alkaline phosphatase in blood plasma, an increase in the concentration of urea in blood plasma.
On the part of the skin and subcutaneous fat: often - itching.
On the part of the nervous system: often - headache, dizziness, weakness; sometimes - drowsiness, insomnia.
On the part of the urinary system: sometimes - polyuria.
On the part of the musculoskeletal system and connective tissue: often - joint pain, exacerbation of gout.

OVERDOSE:
Cases of the drug overdose are not described.

INTERACTION WITH OTHER DRUGS:
Immunosuppressants may decrease the effectiveness of the drug action. Xanthine oxidase inhibitors and uricosuric agents (including diuretics) may enhance the risk of an increase of the serum uric acid level in patients taking Isoprinosine.

PREGNANCY AND LACTATION:
It is not recommended to use the drug during pregnancy and lactation, since the safety of use has not been studied.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
There are no special contraindications.

STORAGE CONDITIONS:
Store at a temperature not exceeding +25 ° C (+77 ° F) in a dry, dark place. Keep out of the reach of children.

SHELF LIFE:
5 years. Do not use beyond the expiration date indicated on the package.

MANUFACTURER:
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