CYCLOFERON®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Cycloferon.

DOSAGE FORM AND STRUCTURE:
Composition (1 tablet):
Active ingredient: meglumine acridone acetate in terms of acridone acetic acid - 150.00 mg obtained according to the following formula: acridone acetic acid - 150.00 mg, meglumine (N-methylglucamine) - 146.00 mg;
Excipients: povidone K 30 - 7.93 mg, calcium stearate - 3.07 mg, hypromellose - 2.73 mg, polysorbate 80 - 0.27 mg;
Enteric coating: methacrylic acid and ethyl acrylate copolymer [1:1] - 23.21 mg, propylene glycol - 1.79 mg.

Composition (1 ampule):

Active ingredient: meglumine acridone acetate in terms of acridone acetic acid - 125.0 mg obtained according to the following formula: acridone acetic acid - 125.0 mg, meglumine (N-methylglucamine) - 96.3 mg;
Excipients: water for injection up to 1.0 ml.

DESCRIPTION:
Tablets: yellow round biconvex tablets with an enteric coating. In the cross section the core is yellow.
Ampules: clear yellow liquid.

ATC CODE: L03AX Other immunostimulants.

PHARMACOLOGICAL ACTION: immunostimulating agent.

PHARMACODYNAMICS:
Cycloferon is a low molecular weight inducer of interferon, which determines a wide range of its biological activity (antiviral, immunomodulatory, anti-inflammatory, etc.).
Cycloferon tablets.
Effective against herpes viruses, influenza and other activators of acute respiratory infections. It has a direct antiviral effect, inhibiting the reproduction of the virus in early stages (1–5 days) of the infectious process, reducing the infectivity of virus progeny, and leading to the formation of defective viral particles. It increases nonspecific resistance of the body against viral and bacterial infections.
Cycloferon in ampoules.
The main producing cells of interferon after an administration of Cycloferon are macrophages, T- and B-lymphocytes. Depending on the type of infection, there is a predominance of activity of a particular immunity link. The drug induces high titers of interferon in organs and tissues containing lymphoid elements (spleen, liver, lungs), and activates bone marrow stem cells, stimulating the formation of granulocytes. Cycloferon in ampoules activates T-lymphocytes and

natural killer cells, normalizing the balance between subpopulations of T-helpers and T-suppressors. It enhances the activity of α-interferons.
Cycloferon ampoules are effective against tick-borne encephalitis viruses, influenza, hepatitis, herpes, cytomegalovirus, human immunodeficiency virus, papilloma virus and other viruses. In acute viral hepatitis, Cycloferon prevents the transition of diseases into a chronic form. At the stage of primary manifestations of HIV infection, it helps to stabilize immunity indicators.
The drug has been found highly effective in the complex treatment of acute and chronic bacterial infections (neuroinfection, chlamydia, bronchitis, pneumonia, postoperative complications, urogenital infections, peptic ulcer disease) as a component of the immunotherapy.
Cycloferon in ampoules shows high effectiveness in rheumatic and systemic diseases of the connective tissue, suppressing autoimmune reactions and providing anti-inflammatory and analgesic effects.

PHARMACOKINETICS:

Cycloferon tablets.
When taking a daily dose, the maximum concentration in blood plasma is reached after 2-3 hours, it gradually decreases by the 8th hour, and after 24 hours Cycloferon is found in trace quantity. The half-life of the drug is 4–5 hours, that is why its administration in the recommended doses does not create conditions for cumulation in the body.
Cycloferon in ampoules.
In case of the introduction of the maximum allowable dose, the maximum concentration in the blood is reached after 1-2 hours, after 24 hours the drug is detected in trace quantity. It penetrates through the blood-brain barrier. The elimination half-life is 4–5 hours. Cycloferon does not have cumulative properties. It does not accumulate in tissues in case of a prolonged use.

INTENDED USES:

Cycloferon tablets.

In adults in complex therapy:
- Flu and acute respiratory infections;
- Herpetic infection.

In children from the age of four in complex therapy:
- Flu and acute respiratory infections;
- Herpetic infection;
- Prevention of influenza and acute respiratory diseases.

Cycloferon in ampoules.

In adults in complex therapy:
- HIV infection (stages 2A - 2B);
- Neuroinfections (serous meningitis and encephalitis, tick-borne borreliosis - Lyme disease);
- Markers of viral hepatitis A, B, C and D;
- Herpes and cytomegalovirus infection;
- Secondary immunodeficiencies associated with acute and chronic bacterial and fungal infections;
- Chlamydial infections;
- Diseases of the musculoskeletal system and connective tissue (rheumatoid arthritis, systemic lupus erythematosus, deforming osteoarthrosis).

In children from the age of four in complex therapy:
- Markers of viral hepatitis A, B, C and D;
- Herpetic infection;
- HIV infection (stages 2A - 2B).

CONTRAINDICATIONS:

Pregnancy, the period of breastfeeding, children under 4 y.o., individual intolerance to the components of the drug, decompensated cirrhosis of the liver.
Caution: please consult your doctor before taking Cycloferon tablets in case of diseases of the digestive system in the acute stage (erosion, stomach ulcers and / or duodenal ulcer, gastritis and duodenitis) and allergic reactions in the history.

DOSAGE AND ADMINISTRATION:

Cycloferon tablets.

Inside, once a day 30 minutes before a meal, without chewing, drinking ½ cup of water, in age dosages:

- Children of 4-6 years old: 150 mg (1 tablet) per intake;
- Children of 7-11 years old: 300-450 mg (2-3 tablets) per intake;
- Adults and children over 12 years old: 450-600 mg (3-4 tablets) per intake.

A repeated course may be conducted 2-3 weeks after the end of the first course.

Adults:

- In the treatment of influenza and acute respiratory infections, the drug is taken on days 1, 2, 4, 6, 8 (the course of treatment is 20 tablets). The treatment should be started at the first symptoms of a disease. In severe influenza, six tablets are taken on the first day. Symptomatic therapy is added (antipyretic, painkillers, expectorants) if required.
- In a herpetic infection, the drug is taken on days 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 (the course of treatment is 40 tablets). The treatment is most effective when the first symptoms of a disease appear.

Children from the age of four:

- In influenza and acute respiratory infections, the drug is taken in age doses on days 1, 2, 4, 6, 8, 11, 14, 17, 20, 23. The course of treatment is from 5 to 10 intakes, depending on the severity of the condition and the severity of clinical symptoms.
- In a herpetic infection, the drug is taken on the 1st, 2nd, 4th, 6th, 8th, 11th and 14th day of treatment. The course of treatment may vary depending on the severity of the condition and the severity of clinical symptoms.
- In emergency non-specific prevention of influenza and acute respiratory diseases (in case of a direct contact with patients who suffer from influenza or acute respiratory infections of other etiologies during the flu epidemic): on days 1, 2, 4, 6, 8. Then there is a break of 72 hours (three days) and after that the course is continued on days 11, 14, 17, 20, 23. The general course is from 5 to 10 intakes.

Cycloferon in ampoules.

Adults:

Cycloferon is used intramuscularly or intravenously once a day according to the basic scheme: every other day. The duration of treatment depends on a disease.

- In herpes and cytomegalovirus infection, the drug is administered according to the basic scheme - 10 injections of 0.25 g each. The total dose is 2.5 g. The treatment is most effective at the onset of the exacerbation of a disease.
- In neuroinfections, the drug is administered according to the basic scheme. The course of treatment is 12 injections of 0.25-0.5 g each in combination with etiotropic therapy. The total dose is 3-6 g. Repeated courses are carried out as necessary.
- In chlamydial infection, the drug is administered according to the basic scheme. The course of treatment is 10 injections of 0.25 g each. The total dose is 2.5 g. A repeated course of treatment is carried out after 10-14 days. It is advisable to combine Cycloferon with antibiotics.

- In acute viral hepatitis A, B, C, D and mixed forms, the drug is administered according to the basic scheme - 10 injections of 0.5 g. The total dose is 5.0 g. In a prolonged course of infection, the treatment is repeated after 10-14 days.
- In chronic viral hepatitis B, C, D and mixed forms, the drug is administered according to the basic scheme - 10 injections of 0.5 g, then according to the maintenance scheme - three times a week for 3 months as part of the complex therapy. It is recommended to combine the drug with interferons and chemotherapy. The course is repeated after 10-14 days.
- In case of HIV infection (stages 2A - 2B), the drug is administered according to the basic scheme - 10 injections of 0.5 g each, then according to the maintenance scheme - once every three days for 2.5 months. The course is repeated after 10 days.
- In immunodeficiency conditions, the course of treatment is 10 intramuscular injections according to the basic scheme in a single dose of 0.25 g. The total dose is 2.5 g. A repeated course is carried out after 6-12 months.
- In rheumatoid arthritis, systemic lupus erythematosus - 4 courses of 5 injections of 0.25 g according to the basic scheme with a break of 10-14 days. A second course is carried out upon the doctor's recommendation.
- In deforming osteoarthritis - 2 courses of 5 injections of 0.25 g each according to the basic scheme with a break of 10-14 days. A second course is carried out upon the doctor's recommendation.

Children over 4 years old:

In pediatrics Cycloferon is used intramuscularly or intravenously once a day according to the basic scheme: every other day. The daily therapeutic dose is 6-10 mg / kg body weight.

- In acute viral hepatitis A, B, C, D and mixed forms, the drug is administered according to the basic scheme - 15 injections. In a prolonged course of infection, the treatment is repeated after 10-14 days.
- In chronic viral hepatitis B, C, D and mixed forms, the drug is administered according to the basic scheme - 10 injections, then according to the maintenance scheme - three times a week for 3 months as part of the complex therapy. It is recommended to combine the drug with interferons and chemotherapy.
- In HIV infection (stages 2A - 2B) - a course of 10 injections according to the basic scheme, then according to the maintenance scheme - once every three days for 3 months. A second course is carried out after 10 days.
- In herpetic infection - a course of 10 injections according to the basic scheme. In case the replicative activity of the virus persists, the treatment is continued according to the maintenance scheme with the introduction of the drug once every three days for four weeks.

PRECAUTION:

Cycloferon tablets.

In case of diseases of the thyroid gland, consultation with an endocrinologist is necessary.
If a dose of the drug is missed, it is necessary to continue the course according to the original scheme as soon as possible without taking into account the time interval and without doubling the dosage.
In the absence of a therapeutic effect, please consult a doctor.

Cycloferon in ampoules.

In case of diseases of the thyroid gland, consultation with an endocrinologist is necessary. Urine may obtain a violet-blue color (luminescence).
If the color of the solution is changed and there is sediment in the vial, the use of the drug is contraindicated.

SIDE EFFECTS:

According to the World Health Organization, side effects are classified according to their frequency of development as follows:

- Very common (≥ 1/10);
- Common (frequent) (≥ 1/100 - <1/10);
- Uncommon (infrequent) (≥ 1/1000 - <1/100);
- Rare (≥ 1/10000 - <1/1000);
- Very rare (<1/10000);
- Frequency unknown (cannot be determined based on available data).

Cycloferon tablets.
Immune system disorders: very rare - angioneurotic edema.
Disorders in skin and subcutaneous tissues: very rare - rash, urticaria.
Cycloferon in ampoules.
General disorders at the injection site: very rare - chills, fever, pain and redness at the injection site.
Disorders in skin and subcutaneous tissues: very rare - rash, urticaria.

If any of the undesirable effects specified in the instructions are exacerbated or if you notice any other undesirable effects not listed in the instructions, inform your doctor.

OVERDOSE:
There are no data on the drug overdose.

INTERACTION WITH OTHER DRUGS:
Cycloferon is compatible with all drugs used in the treatment of the indicated diseases (interferons, chemotherapeutic drugs, etc.). It enhances the action of interferons and nucleoside analogues. It reduces the side effects of chemotherapy and interferon therapy.

PREGNANCY AND LACTATION:
The drug administration during the pregnancy and lactation is contraindicated.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
Cycloferon does not affect the ability to drive vehicles.

STORAGE CONDITIONS:
Keep in a dark place at a temperature from 0 to 25°C (77°F). Keep out of the reach of children.

SHELF LIFE:
Cycloferon tablets: 2 years.
Cycloferon in ampoules: 5 years.
Do not use after the expiry date indicated on the package.

MANUFACTURER: POLYSAN Scientific & Technological Pharmaceutical Company (LLC NTFF POLISAN), https://eng.polysan.ru/