

INSTRUCTION

CYCLOFERON ENTERIC-COATED TABLETS, 0.15 g

TRADE NAME: CYCLOFERON.

THERAPEUTIC CATEGORY: Immunomodulating factor (inducer of interferon)

DOSAGE FORM: enteric-coated tablets, 0.15 g.

COMPOSITION:

Acridone acetic acid – 0.15 g,

N-methylglucamine – 0.146 g.

Adjuvants: methylcellulose, calcium stearate.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics. Cycloferon is a low-molecular-weight inducer of interferon, which defines a wide range of its biological activities (antiviral, immunomodulating, anti-inflammatory, antiproliferative, antineoplastic etc.) The medicine induces high titers of α - and β -interferon in organs and tissues, containing lymphoid elements (mucous of small intestine, spleen, liver, and lungs), and crosses the blood-brain barrier. Cycloferon is very competent at curing diseases caused by viruses of tick-borne encephalitis, influenza, hepatitis, herpes, cytomegalovirus, human immunodeficiency virus (HIV), and various enteroviruses. It amplifies the antibacterial action of antibiotics used in therapy of acute enteric infection. The medicine acts as anticarcinogenic and anti-metastatic drug, thus preventing the formation of tumors through the activation of immune response in organism. Immunomodulating action of Cycloferon is manifested both as activation of phagocytosis, of cytotoxic T-cells and natural-killer-cells and as organism immune status correction at immunodeficiency disorders of different genesis.

Pharmacokinetics. When given a maximum permissible dose, the maximum concentration in plasma is achieved in 2-3 hours; concentration is gradually decreased in 8 hours. In 24 hours Cycloferon is present only in trace quantity. The half-life of the medicine is 4-5 hours. Thus, the administration of Cycloferon in recommended doses does not lead to its accumulation in organism.

INDICATIONS

In adults Cycloferon is recommended during combined therapy of:

- herpes infections,
- acute enteric infection,
- chronic viral hepatitis B and C,
- influenza and acute respiratory infections,
- neural infections (aseptic (serous) meningitis, Lyme disease),
- HIV infection (stages 2A-3B),
- secondary immunodeficiency, associated with chronic bacterial and fungal infections.

In children over 4 years old Cycloferon is recommended during combined therapy of:

- acute and chronic hepatitis B and C,
- herpes infections,
- preventive treatment and therapy of influenza and acute viral respiratory infections,
- acute enteric infections,
- combined therapy of HIV infection (stages 2-3B)

ADMINISTRATION AND DOSAGE

Cycloferon is administered once a day half-hour before meal by swallowing it whole.

For adults:

1. In herpes infection the medication should be taken in a single dose of 2-4 tablets on the 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 day (3.0-6.0 g, 20-40 tablets per course of treatment). The therapy should be started early in aggravation of the disease.

2. In influenza and acute respiratory infections the medicine is taken in a single dose of 2-4 tablets on the 1, 2, 4, 6, 8 day (1.5-3.0 g, 10-20 tablets per course of treatment). The therapy must be started when the first symptoms of infection become obvious. In severe cases of the disease 6 tablets on the first day of therapy should be taken. Additionally, symptomatic therapy (antipyretics, analgesics, and expectorants) can be instituted, if necessary.
3. In chronic viral hepatitis B and C the medicine is taken in a single dose of 4 tablets on the 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 day. Should replicating and cytolytic activities of the disease process persist, then maintenance dose once in every three to five days for 2.5 months should follow (100-150 tablets per course of treatment). In chronic hepatitis C and mixed hepatitis the therapeutic cure must be repeated ones or twice one month later upon completion of the previous course of treatment. Use in combination with interferons and antiviral preparations is advisable.
4. In combined therapy of enteric infections, following the standard treatment regimen in a single dose of 2 tablets on the 1, 2, 4, 6, 8 day the treatment in a single dose of 2 tablets on the 11, 14, 17, 20, 23 day should be instituted (3.0 g, 20 tablets per course of treatment).
5. In neural infections the standard treatment regimen should be instituted in a single dose of 4 tablets on the 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 day. Then the maintenance dose of 4 tablets once in every five days for 2.5 months should follow (15.0 g, 100 tablets per course of treatment).
6. In HIV infection (stages 2A-3B) the medicine must be taken in a single dose of 4 tablets on the 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 day. The maintenance therapy should follow up then in a single dose of 4 tablets once in three to five days for 2.5 months (100-150 tablets per course of treatment). The course of treatment should be repeated in 2-3 weeks after the previous course of treatment was completed.
7. In immunodeficiency the course of treatment by the standard regimen - a single dose of 2 tablets on the 1, 2, 4, 6, 8, 11, 14, 17, 20, 23 day (3.0 g, 20 tablets per course of treatment).

For children:

Cycloferon is administered under the following standard regimen:

Age (years)	Dosage (mg)	Number of tablets (single dose)
4 – 6	150	1
7 – 11	300	2
over 12	450	3

The second course of treatment is appropriate in 2-3 weeks after the first treatment.

1. In acute viral hepatitis B and C the medicine is taken in above stated doses at intervals of 24 hours (2 administrations), then at intervals of 48 hours (3 administrations), and then at intervals of 72 hours (5 administrations) (10-30 tablets per course of treatment, age depending).
2. In chronic forms of hepatitis B and/or C the medication is taken in above stated doses at interval of 48 hours (50-150 tablets per course of treatment, age depending).
3. In HIV infection (stages 2A-3B) the medication is taken under the standard regimen on 1, 2, 4, 6, 8, 11, 14, 17, 20 day and then once in every three to five days for five months.
4. In herpes infections the medication is taken on the 1, 2, 4, 6, 8, 11, 14 day. The treatment course length can vary depending on health and clinical status.
5. In acute enteric infections the medication is taken in a single dose on the 1, 2, 4, 6, 8, 11 day (6-18 tablets per course of treatment).
6. For express nonspecific prophylaxis of acute respiratory infections and influenza during the periods of increased incidence rate the medicine is taken in above stated doses on the

- 1, 2, 4, 6, 8 day followed by 5 more administrations at intervals of 72 hours (10-30 tablets per course of treatment).
7. In acute viral respiratory infections the medicine is taken in a single dose at intervals of 24 hours. The course of treatment consists of 5-9 administrations.

ADVERSE REACTIONS

Sensitization to any of the components of this preparation is a possibility.

CONTRAINDICATIONS

The medicine is not recommended during periods of pregnancy and lactation. The medicine is not recommended to persons with uncompensated hepatic cirrhosis.

SPECIAL DESIGNATIONS

In inflammation of the thyroid gland the administration of Cycloferon should be conducted under endocrinologist supervision.

DRUG INTERACTIONS

Cycloferon is compatible with all the medicines traditionally used in therapy of the above mentioned diseases (interferons, chemotherapeutic agents etc.).

HOW SUPPLIED

Tablets of yellow or golden-brown color. Each tablet contains 0.15 g of active substance with enteric coating. Tablets are supplied in blisters by 10 or in bottles by 50. Blisters and bottles are packed in carbon boxes. Each pack contains 10 or 50 tablets.

STORAGE

The medicine should be stored in dry, light protected place at usual conditions. The medicine should be stored in places not to be reached by children.

TERMS

Shelf life is 2 years from the date of manufacture.

**Read the instruction carefully before using. Ask your physician for more information.
Keep out of the reach of children. By prescription only.**