Instructions for use

Trade name: Anaferon

Pharmaceutical form: orodispersible tablets

Composition: Each orodispersible tablet contains:

Active ingredient: Affinity purified antibodies to human gamma interferon – 0.003 g*

Excipients: lactose, microcrystalline cellulose, magnesium stearate.

* – Water-ethanol mixture of the active substance dilutions with concentration not more than $10^{-15}$ ng/g used for saturation of lactose.

Pharmacotherapeutic group

Immunomodulators. Antivirals.

Pharmacological properties

Pharmacodynamics: The medicine exerts immunomodulatory and antiviral effects upon prophylactic and therapeutic administration. Effectiveness is established experimentally and clinically towards influenza viruses (including bird flu), parainfluenza viruses, herpes simplex virus of type 1 and 2 (labial herpes, genital herpes), other herpes virus diseases (varicella, infectious mononucleosis), enterovirus, tick-borne encephalitis virus, rotavirus, coronavirus, calicivirus, adenovirus, respiratory syncytial virus. The drug reduces the concentration of virus in the affected tissues, influences on the system of endogenous interferons and related cytokines, induces the production of endogenous "early" interferons (IFN α/β) and gamma interferon (IFNγ).

The drug stimulates humoral and cell-mediated immune responses. Anaferon increases antibody production (including secretory IgA), activates the functions of T-effectors and T-helpers (Th) and normalizes their ratio. The drug increases the functional reserves of Th and other cells involved in the immune response. The drug induces combined Th1 and Th2-type immune response through enhancing the production of Th1 (IFNγ, IL-2) and Th2 (IL-4, 10) cytokines, normalizes (modulates) the Th1/Th2 activity balance. The drug increases the functional activity of phagocytes and natural killer cells (NK cells). The drug also possesses antimutagenic properties.

Pharmacokinetics: The sensitivity of contemporary physicochemical methods (gas-liquid chromatography, high performance liquid chromatography and mass spectrometry) does not allow to assess the content of ultralow doses of antibodies in biological fluids, organs and tissues, that makes technically impossible to investigate the pharmacokinetic properties of Anaferon.

Therapeutic indications

Prophylaxis and treatment of acute viral respiratory infections (including influenza).

Complex therapy of infections caused by herpes viruses (infectious mononucleosis, varicella, labial herpes, genital herpes).

Complex therapy and prophylaxis of relapses of chronic herpes virus infection including labial and genital herpes.
Complex therapy and prophylaxis of other acute and chronic viral infections caused by tick-borne encephalitis virus, enterovirus, rotavirus, coronavirus, calicivirus.

Used in a complex therapy of bacterial infections.

Complex therapy of secondary immunodeficiencies of various etiology including prophylaxis and treatment of complications of virus and bacterial infections.

Contraindications

Individual hypersensitivity to components of the medicine.

Posology and method of administration

Oral route.

One tablet per intake (the tablet should be held in the mouth until it is completely dissolved, not during the meal).

URI’s, influenza, intestinal infections, herpes virus infections, neuroinfections.

Treatment should begin as early as possible - beginning from the first onset of symptoms of an acute viral infection according to the following regimen: 1 tablet is taken every 30 minutes during the first 2 hours, then 3 more tablets of Anaferon should be administered in equal time intervals during the first day of treatment. Beginning from the second day of treatment 1 tablet is administered 3 times a day until full recovery.

If no improvement occurs by the third day of treatment of acute respiratory virus infections and influenza, a doctor should be consulted.

Throughout the epidemic season for prophylaxis purposes the drug is administered 1 tablet daily for 1-3 months.

Genital herpes. In cases of acute manifestations of genital herpes the drug is taken in equal time intervals according to the following regimen: 1-3 days - 1 tablet is taken 8 times/day, furthermore 1 tablet is taken 4 times/day for not less than 3 weeks.

For the prophylaxis of relapses of chronic herpes virus infections – 1 tablet is taken daily. The recommended duration of the prophylactic course should be defined individually and may reach 6 months.

When administering the drug for treatment and prophylaxis of immunodeficiencies, in the complex therapy of bacterial infections – 1 tablet is administered daily.

If necessary Anaferon can be co-administered with other antiviral and symptomatic drugs.

Children are persons under 18 years should administer Anaferon for children.

Undesirable effects

No side effects have been reported for the drug used in accordance with the specified indications in the recommended doses.

Individual hypersensitivity to components of the medicine is possible.

Inform doctors of any unwanted effects related to drug use.
Overdose

No cases of overdose have been reported.

Dyspepsia caused by excipients is possible in accidental overdose.

Effects on ability to drive and use machines

Anaferon has no influence on the ability to drive and use machines.

Interaction with other medicinal products and other forms of interaction

Cases of incompatibility with other medicines have not been reported. If necessary the drug can be co-administered with other antiviral, antibacterial and symptomatic drugs.

Special warnings and precautions for use

Medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Use in Pregnancy and lactation

There were no special clinical studies of Anaferon on woman in period of pregnancy or lactation.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition of postnatal development.

Caution should be exercised when prescribing to pregnant women.

Nature and contents of container

20 orodispersible tablets in PVC/Aluminum blister. 1 blister is inserted into a cardboard box with leaflet.

Storage conditions

Store in dry light-protected place at temperature below 30°C.

Store in the original package.

Keep out of reach of children.

Dispensing rules

Over the counter.

Shelf life

3 years since the manufacturing date. Do not use after the expiry date indicated on the package.