Read this information carefully before using this medicine.
Ask your doctor or pharmacist if you need further information.

AFFINITY-PURIFIED ANTIBODIES TO HUMAN INTERFERON GAMMA

ANAFERON

3 mg* Orodispersible Tablet
Antiviral

Formulation

Each orodispersible tablet contains:
Active ingredient: Affinity-purified antibodies to human interferon gamma - 3 mg*.
** Water-ethanol mixture of the active substance dilutions (C12, C30 & C50) with concentration not more than 10^{-16} ng/g used for saturation of lactose monohydrate.*
Excipients: lactose monohydrate, microcrystalline cellulose, magnesium stearate.

Description

White to off-white, round, flat, scored on one side and beveled tablets, marked MATERIA MEDICA on one side and ANAFERON KID on the other.

Pharmacotherapeutic group

Antivirals.
ATC codes: J05AX.

Pharmacological properties

Pharmacodynamics: The medicine exerts antiviral effects upon prophylactic and therapeutic administration. Effectiveness is established experimentally and clinically towards influenza viruses, 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 a/β) and interferon gamma (IFN γ).
The drug stimulates humoral and cell-mediated immune responses. Affinity-purified antibodies to human interferon gamma (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 Thl (IFN γ, IL-2) and Th2 (IL-4, 10) cytokines, normalizes (modulates) the Thl/Th2 activity balance. The drug increases the functional activity of phagocytes and natural killer cells (NK cells).
Pharmacokinetics: The sensitivity of contemporary physicochemical methods (gas-liquid chromatography, high performance liquid chromatography and mass spectrometry) does not allow assessing the content of active components of the drug in biological fluids, organs and tissues, that makes technically impossible to investigate the pharmacokinetic properties of Affinity-purified antibodies to human interferon gamma (Anaferon).

Therapeutic indications

Prophylaxis and treatment of influenza for children (6 months - 14 years).

Dosage and administration

Oral route.
Affinity-purified antibodies to human interferon gamma (Anaferon) should be administered by children from 6 months to 14 years of age.
One tablet per intake (the tablet should be held in the mouth until it is completely dissolved, not during the meal).

When indicated to younger children (6 months - 3 years old) the tablet is recommended to be dissolved in a small volume (a tablespoonful) of drinking water at room temperature.
Influenza.
On day 1, five tablets are taken in the first 2 hours (one tablet every 30 min), followed by three more tablets regularly spaced during the rest of the day. From day 2, one tablet is taken three times daily until complete 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.
If necessary Affinity-purified antibodies to human interferon gamma (Anaferon) can be co-administered with other antiviral and symptomatic drugs.
Affinity-purified antibodies to human interferon gamma (Anaferon) is not recommended for use in children below age of 6 months due to a lack of data on safety and efficacy.

Contraindications

Individual hypersensitivity to components of the medicine.

Adverse effects

Allergic reactions and individual hypersensitivity to components of the medicine are possible.

Inform doctors of any unwanted effects related to drug use.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Overdose

Overdose of this product can cause dyspeptic disorders due to excessive intake of excipients. Treatment should be symptomatic.

Effects on ability to drive and use machines

Affinity-purified antibodies to human interferon gamma (Anaferon) has no or negligible 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 monohydrate. 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

Pregnancy

There are no or limited amount of data from the use of Affinity-purified antibodies to human interferon gamma (Anaferon) in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive/foetal toxicity. As a precautionary measure, it is preferable to avoid the use of Affinity-purified antibodies to human interferon gamma (Anaferon) during pregnancy.

Lactation

It is unknown whether Affinity-purified antibodies to human interferon gamma (Anaferon) and/or its metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Affinity-purified antibodies to human interferon gamma (Anaferon) should not be used during breast-feeding.

Storage condition

Store at temperatures not exceeding 30 °C.

Keep out of reach of children.

Availability

In a box of 1-PVC/Alu blister pack x 20's

Caution
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Manufactured by:
OOO «NPF «MATERIA MEDICA HOLDING»,
54, Buguruslanskaya Str, Chelyabinsk, 454139, Russia

Imported by: **MEGA LIFESCIENCES LIMITED INC.** 3rd Floor, ACE Building, 101 Rada Street, Legaspi Village, Makati City, Philippines	Distributed by: **METRO DRUG, INC.** Sta. Rosa Estate, Barangay Macabling, Santa Rosa, Laguna, Philippines

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