IMUNOFAN®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Arginyl-alpha-aspartyl-lysyl-valyl-tyrosyl-arginine

DOSAGE FORM AND STRUCTURE:

Spray

Active ingredient: Arg-α-Asp-Lys-Val-Tyr-Arg diacetate (in terms of anhydrous and acetic acid-free substance) - 45 mcg / dose;

Excipients: glycine (5 mg); sodium chloride (0.7 mg); benzalkonium chloride (0.014 mg); disodium edetate (0.007 mg); purified water (up to 0.14 ml).

Solution

Active ingredient: Arg-α-Asp-Lys-Val-Tyr-Arg diacetate (in terms of anhydrous and acetic acid-free substance) - 45 mcg;

Excipients: glycine (5 mg); sodium chloride (9 mg); water for injection (up to 1 ml).

DESCRIPTION:

Nasal spray. Transparent or almost transparent, colourless or slightly yellowish liquid. A slight characteristic smell is allowed.

Solution for intramuscular and subcutaneous administration. Clear, colorless solution for injections in ampoules.

ATC CODE: L03 Immunostimulants

NOSOLOGICAL CLASSIFICATION (ICD-10):

- A07.2 Cryptosporidiosis
- A23.9 Brucellosis, unspecified
- A36.9 Diphtheria, unspecified
- A74.9 Chlamydial infection, unspecified
- B00.9 Herpesviral infection, unspecified
- B18.9 Chronic viral hepatitis, unspecified
- B24 Unspecified human immunodeficiency virus [HIV] disease
- B25.9 Cytomegaloviral disease, unspecified
- B58.9 Toxoplasmosis, unspecified
- B59 Pneumocystosis
- C80 Malignant neoplasm, without specification of site
- C96.9 Malignant neoplasm of lymphoid, haematopoietic and related tissue, unspecified
- D84.9 Immunodeficiency, unspecified
- J38.1 Polyp of vocal cord and larynx
- J44.8 Other specified chronic obstructive pulmonary disease
- L40 Psoriasis
- M06.9 Rheumatoid arthritis, unspecified
- T30 Burn and corrosion, body region unspecified
- Z22.2 Carrier of diphtheria
- Z29.1 Prophylactic immunotherapy

PHARMACOLOGICAL ACTION: Immunomodulatory

PHARMACODYNAMICS:

The drug has immuno-regulatory, detoxifying, hepatoprotective effects and participates in the processes of inactivation of free radicals. Pharmacological action is based on three main effects: 1) immunocorrection (i.e. correction of the deficiency of the immune system), 2) normalization of the oxidative processes of the organism and 3) inhibition of the multidrug resistance mediated by the transmembrane transport pump proteins of the cell.

The direct effect of the medication develops during the first 2-3 h after an injection, lasts up to 4 months and consists of several phases: Fast, Intermediate and Slow.

- During the Fast phase (continuing up to 2-3 days) Imunofan activates anti-oxidative ability of the organism thus preventing free radical formation and damage of the cellular membranes. At this time the detoxifying effect becomes apparent and the organism antioxidant defense is increased by the stimulation of a number of physiologically active compounds that prevent the cascade radical formation in the cellular membrane. The preparation inhibits the cleavage of the cell membrane phospholipids and decreases oxidized low density lipoproteins and synthesis of arachidonic acid with the following decrease of blood cholesterol levels and production of inflammatory mediators, prostaglandins and leukotrienes. Imunofan can protect lymphocyte DNA from the peroxide damage. The preparation prevents cytolysis and decreases transaminase activities and bilirubin levels in the blood of patients with toxic or infectious hepatitis.
- During the Intermediate phase (starting 2-3 days after an injection and lasting up to 7-10 days) the increase of phagocytosis and activation of the oxygen-dependent neutrophil antibacterial system occur. These effects are produced by the elevation of the hidden capacities of neutrophils to kill and eliminate intracellular bacteria and viruses, and by the increase in expression of HLA-DR molecules on the surface of T-cell, which leads to better recognition of antigen presentation by macrophages and lends a helping-effect to B-cell. These developments occur on the background of the recovery of interleukines, interferon-α or -γ production and TNF production normalization.
- During the Slow phase (starting after 7-10 days and lasting up to 4 months) the immunoregulatory effect of the drug becomes apparent. Imunofan restores broken cellular and humoral immunity by the stimulation of the process of T-lymphocytes maturation and recovery of the Th1/Th2 lymphocytes balance. At this time an increase of specific IgM, IgG and IgA production may be observed. The influence of the preparation on the production of specific antiviral and antibacterial antibodies is similar to the effect of some therapeutic vaccinations, except with lesser if any influence on the production of IgE and acute type hypersensitivity. As a premedicant drug in vaccination of patients with severe allergic diseases Imunofan allows reducing hyperproduction of IgE and raises early protective properties of vaccines with low content of antigen.

Imunofan effectively suppresses the multidrug resistance of tumor cells and improves their sensitivity to the action of cytostatic drugs.

INTENDED USES:

Prevention and treatment in adults and children over two years old:

- Immunodeficiency and toxic conditions;
- Chronic inflammatory diseases of various etiologies.

CONTRAINDICATIONS:

- Idiosyncrasy;
- Rh-incompatible pregnancy;
- Child age (under 2 years old).

DOSAGE AND ADMINISTRATION:

Spray

Intranasal administration. During the administration the bottle should be held vertically, spray up.

1. Remove the protective cap from the spray dispenser.
2. Before the first use, fill the dosing pump by pressing the wide rim of the sprayer 3-4 times.
3. Insert the spray device into the nasal passage with the head upright;
4. Press back the wide rim of the spray once.

1 dose contains 45 mcg of Imunofan. The daily dose should not exceed 180 mcg.

- In the complex treatment of acute and chronic infectious and inflammatory diseases accompanied by symptoms of intoxication and immunodeficiency: 1 dose (45 mcg) in each nasal passage 2 times a day, daily for 10-15 days.
- In opportunistic infections (cytomegalovirus and herpetic infections, toxoplasmosis, chlamydiosis, pneumocystosis, cryptosporidiosis): 1 dose (45 mcg) in each nasal passage 2 times a day, daily for 10-15 days. If necessary, the course may be repeated after 2-4 weeks.
- In case of chronic viral hepatitis and chronic brucellosis: 1 dose (45 mcg) in each nasal passage 1 time per day, daily for 10-15 days, to prevent relapse, repeated courses should be taken after 4-6 months.
- In the treatment of HIV patients: 1 dose (45 mcg) in each nasal passage 1 time per day, daily for 10-15 days. If necessary, the course may be repeated after 2-4 weeks.
- In the treatment of cancer patients in a radical combination treatment scheme (chemoradiation therapy and surgery): 1 dose (45 mcg) in each nasal passage 1 time per day, daily for 8-10 days before the chemoradiation therapy and surgery with subsequent continuation of the course throughout the entire period of treatment.
- In patients with an advanced tumor process (stages III-IV) of various localization in complex or symptomatic therapy: 1 dose (45 mcg) in each nasal passage 1 time per day, daily for 8-10 days. If necessary and in the presence of pronounced symptoms of toxicosis, a repeated course is recommended.

Solution

Imunofan is prescribed subcutaneously or intramuscularly, in courses. Single and daily dose - 45 mcg.

In adults:

- In the treatment of cancer patients in the radical combined treatment scheme: 1 time per day, daily, the course of treatment is 8-10 injections before the chemoradiation therapy and surgery, followed by the continuation of the course throughout the entire treatment period.
- In patients with an advanced tumor process: 1 time per day, daily, the course of treatment is 8-10 injections with a break of 15-20 days. The course is repeated throughout the entire period of the subsequent treatment.
- In case of chronic viral hepatitis and chronic brucellosis (complex treatment): 1 time per day, daily, the course of treatment is 15-20 injections.
- In the complex treatment of HIV infection and opportunistic infections: 1 time per day, daily, the course of treatment is 15-20 injections. If necessary, the course can be repeated in 2-4 weeks.
- In surgical patients, in the treatment of burns of the III-IV degree with phenomena of toxemia, septicotoxemia, in surgical patients with septic endocarditis, cholecystic pancreatitis, long-term healing of limb wounds, purulent-septic complications: 1 time per day, daily, the treatment is 7-10 injection. If necessary, the course should be continued up to 20 injections.
- In bronchial obstructive syndrome, rheumatoid arthritis: 1 time every 3 days, the course of treatment is 8-10 injections. If necessary, the course should be continued up to 20 injections.
- In the complex treatment of psoriasis: 1 time per day, daily, the course of treatment is 15-20 injections.

- In diphtheria: 1 time per day, daily, the treatment course is 8-10 injections. In diphtheria bacteria carrying: 1 time every 3 days - 3-5 injections.
- As an adjuvant for vaccination against bacterial and viral infections: 1 dose of 45 mcg intramuscularly or subcutaneously on the day of vaccination.

For adults and children over 2 years old in the complex treatment of inflammatory eye diseases:

- In lesions of anterior eye sections (keratitis, keratouveitis): 1 time per day, daily, the course of treatment is 7-10 injections.
- In lesions of posterior eye sections (peripheral, posterior uveitis, retinovasculitis) and in generalized inflammatory processes: 1 time per day, daily, the course of treatment is 15-20 injections.

In children over 2 years old:

- In the complex therapy of children with larynx and oropharynx papilomatosis: 1 time per day, daily, 10 injections.

For prevention:

- Exacerbations of chronic viral hepatitis and chronic brucellosis in adults and children over 2 years old: 1 time per day, daily, with a course of 15-20 injections, repeated preventive courses are recommended every 2-3 months;
- The development of toxicosis in children over 2 years old with malignant diseases of hematopoietic and lymphoid tissue: 1 time per day, daily, the course of treatment is 10-20 injections. The treatment should be carried out during the entire course of the chemoradiation therapy and after it.

PRECAUTION:

As a result of phagocytosis activation, a short-term exacerbation of chronic inflammation is possible supported by the persistence of viral or bacterial antigens.

SIDE EFFECTS:

Although unlikely, Imunofan may cause insignificant inflammatory reactions in certain individuals. Therefore, before using this drug, tell your doctor if you have any autoimmune diseases or drug idiosyncrasy.

OVERDOSE:

Cases of the drug overdose have not been recorded.

INTERACTION WITH OTHER DRUGS:

The drug increases the effectiveness of other types of drug therapy. Imunofan helps to overcome resistance to glucocorticosteroid therapy. The prescription of the drug is possible in combination with anti-inflammatory steroid and non-steroid anti-inflammatory drugs.

PREGNANCY AND LACTATION:

The drug should not be used during pregnancy complicated by Rh-conflict. During pregnancy and breastfeeding, the drug can be used only if the intended benefit to the mother outweighs the potential risk to the fetus and the baby.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:

The drug does not affect the ability to drive vehicles and operate mechanisms.

STORAGE CONDITIONS:

The drug is stored in a dark place at a temperature from 2°C (35.6°F) to 8°C (46.4°F), out of the reach of children. Do not freeze.

SHELF LIFE: 2 years. Do not use after the expiry date indicated on the package.

MANUFACTURER: BIONOX Co., Ltd., http://www.imunofan.ru/eng/imunofan_eng.html