

## **IMUNOFAN (IMUNOFANUM)**

(registration number 000106/02)

Sterile Solution for  
Parenteral Use Only

### **USES**

Imunofan is a medication used for treatment of immunological disorders including immunodeficiency.

### **DESCRIPTION**

Imunofan is a clear, colorless solution for injections provided in ampoules, which contains as an active pharmacological substance hexapeptide Arg- $\alpha$ -Asp-Lys-Val-Tyr-Arg with molecular weight 836 D. The preparation is indicated for use as a prophylactic and treatment of immunodeficient states with multiple etiology and diseases followed by immune disorders in adult and children.

### **INDICATIONS**

#### **Carcinogenesis**

Imunofan is an effective drug-component in the treatment of patients with local tumors subjected to complex radical therapy such as surgery, chemo- and radiation therapy. It may be used for both the prevention and the correction of side effects of anticancer treatment. The medication should be used before and after the course of chemo-radiotherapy. It may be indicated in the patients with disseminated (IV stage) cancer for symptomatic therapy, cancer intoxication treatment and improvement oncological patients' quality of life. Imunofan may be an effective drug-component in children suffers from acute and chronic oncohematologic diseases: lymphoblastic lymphadenosis, acute lymphadenosis, malignant lymphoma, lymphogranulomatosis subjected to chemotherapy and complicated toxic or viral hepatitis, pneumonia, sepsis. It may be used in complex therapy of children with papillomatosis larynx.

#### **Acute and Chronic Pyogenic Infections**

Imunofan is a drug of choice, that may be used in combination with specific anti-bacterial therapy, in the treatment of toxic, viral and traumatic disorders of the blood stream, meningitis, heart, lung, joints, liver and pancreas, complicated by septic and/or pyemic microorganisms.

##### **Opportunistic Infections**

It may be indicated in serious infections caused by strains of the following organisms, when interferon- $\alpha$  or other drugs of pathogenetic therapy are ineffective or contraindicated:

Cytomegalovirus Toxoplasma gondii

Klebsiella pneumonia Herpesvirus

Chlamydiae HIV-infectious

Cryptococcus neoformans

Imunofan may be an effective drug-component in the treatment of different stages of AIDS to complex chemotherapy. It causes an effective protection of the immune system from the damaging effects of the free radical compounds with following improvement of Th1/Th2 balance, decreasing of tumor necrosis factor (TNF) production and reduction of manifestation the toxic reactions.

#### **Acute and Chronic Viral Hepatitis**

Imunofan is a drug of choice in the treatment of hepatitis B and C that may be used in patients with contraindication to interferon therapy and high activity of pathological process in liver. Imunofan administration leads to decrease of transaminase activity and decrease the level of bilirubin. The activation of antiviral immunity under the action of the preparation leads to decrease of viral expression.

#### **Inflammatory Eye Diseases**

Imunofan is an effective drug of pathogenetic therapy in the patients with active and chronic inflammatory eye diseases of different etiology and localizations: viral and bacterial keratitis, acute, chronic and recurrent uveitis, chorioretinitis. It can be used in combination with specific therapy and steroids. Imunofan application eliminates negative immunological disorders and provides the prolonged remission, improves the clinical results and the visual functions.

#### **Diphtheria**

Imunofan is a drug of choice that may be used in the patients with allergic reactions and contradiction to diphtheria antitoxin treatment.

#### **Vaccination**

Imunofan is effective immunologic adjuvant that may be used in combination with specific vaccination (especially with low content of antigen) of the patients with heavy allergic diseases.

#### **Psoriasis**

It may be an effective drug-component in the treatment of different variations psoriasis to complex therapy.

### **HOW TO TAKE THIS MEDICATION**

This medication must be used as directed. One intramuscular, subcutaneous or paraocular (in case of inflammatory eye diseases) injection per day. Injections may be given every 24-48 hours; however, the total number of injections not exceed 20 per course. In according with etiology, length, complications, relapse, etc. of disease the course of injection may be repeated after 1-6 months.

### **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.

## **PRECAUTIONS**

Tell your doctor your medical history, especially Rh-incompatible pregnancy, autoimmune diseases.

## **CONTRADICTIONS**

Rh-incompatible pregnancy, idiosyncrasy.

## **DRUG INTERACTIONS**

Inform your doctor about the medicines you may use (both prescription and nonprescription). Avoid use of any drugs affecting immunomodulation or biostimulation, including alcohol.

## **STORAGE**

Store away from sunlight and moisture at temperature 2-8°C. **Do not freeze.**

## **ADDITIONAL INFORMATION**

Imunofan generates the triggering signal in the target-cells. The preparation is quickly and completely absorbed at the site of administration and is rapidly cleaved to amino acids. Imunofan increases and regulates immunoresponce of human organism and participates in the processes of inactivation of free radicals. Therefore, pharmacological impact of this medication is based on two primary effects – immunocorrection (i.e. correction of deficiency of the immune system) and normalization of the oxidative processes of the organism.

The direct effect of the medication develops during first 2-3 h after injection and 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 organism thus preventing of free radical formation and damage of cellular membranes. At this time the detoxify effect becomes apparent and the organism's antioxidant defense is increased by the stimulation a number of physiologically active compounds, that prevent the cascade radical formation in the cellular membrane. The preparation inhibits the cleavage of cell membrane phospholipids, decreases of oxidized low density lipoproteins and synthesis of arachidonic acid with the following decrease of blood cholesterol levels and production of the inflammatory mediators, prostaglandins and leukotrienes. The Imunofan may 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 after 2-3 days after injection and lasting up to 7-10 days) the increase of phagocytosis and activation of the oxygen-dependent neutrophils antibacterial system are occurring. These effects are produced by the elevation of hidden capacities of the 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- $\alpha$  or  $\gamma$  production and normalizing the production of TNF.

During the **Slow phase** (starting after 7-10 days and lasting up to 4 months) the immunoregulatory effect of the drug becomes apparent. Imunofan reconstructs broken cellular and humoral immunity by the stimulation of the process of T- lymphocytes maturation and recovery the balance from Th1 and Th2 lymphocytes. 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 therapeutical vaccinations, except with lesser if any influence on the production of IgE and acute type hypersensitivity. As premedicant drug at vaccination of the patients with heavy allergic diseases Imunofan allows to reduce hyperproduction of IgE and raises early protective properties of vaccines with low content of antigen.

Since Imunofan action does not depend on the production of PGE2 its administration is possible in combination with steroid and non-steroid anti-inflammatory drugs.

## **CAUTION**

**OPEN SOLUTION OF MEDICATION SHOULD BE STORED UNDER REFRIGERATION. IF UNUSED SHOULD BE DISCARDED AFTER 72 HOURS.PREPARATION SHOULD NOT BE USED AFTER EXPIRATION DATE.**

## **SUPPLIED**

Imunofan is supplied in 1 ml ampoules containing 0.005% sterile solution for subcutaneous and intramuscular injections.

## **PRODUCTION**

BIONOX Co., Ltd.

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