Polyoxidonium®

Dosage Form: Lyophilisate for a solution for injections and local administration
Structure: In a 1 vial.:
Active ingredient: Azoximer bromide - 3/6 mg;
Excipients: mannitol - 0.9 / 1.8 mg; povidone K17 - 0.6 / 1.2 mg
Description:
Porous mass of white or white with a yellowish tint color.

Pharmacological classification: Immunostimulant

ATC code: L03
Pharmacological action:
anti-inflammatory, antioxidant, detoxifying, immunomodulating

Pharmacodynamics

Azoximer bromide has a complex effect: immunomodulating, detoxifying, antioxidant, moderate anti-inflammatory.

The main immunomodulating mechanism of azoximer bromide is the direct effect on phagocytic cells and natural killer cells, as well as the stimulation of antibody formation, synthesis of interferon-alpha and interferon-gamma.

Detoxification and antioxidant properties of azoximer bromide are largely determined by the structure and high molecular nature of the drug. Azoximer bromide increases the body resistance to local and generalized infections of bacterial, fungal and viral etiology. It restores the immunity in secondary immunodeficiency conditions caused by various infections, injuries, and complications after surgical operations, burns, autoimmune diseases, malignant neoplasms, by the use of chemotherapeutic agents, cytostatics, steroid hormones.

A characteristic feature of azoximer bromide in local (intranasal, sublingual) use is the ability to activate factors of the body's early protection from the infection: the drug stimulates bactericidal properties of neutrophils and macrophages, enhances their ability to absorb bacteria, increases bactericidal properties of saliva and the secretion of the upper respiratory tract mucosa.

Azoximer bromide blocks soluble toxic substances and micro particles, it has the ability to remove toxins and salts of heavy metals from the body, it inhibits lipid peroxidation, both by intercepting free radicals and by eliminating catalytically active Fe2+ions.

Azoximer bromide reduces the inflammatory response by normalizing the synthesis of pro- and anti-inflammatory cytokines. Azoximer bromide is well tolerated, does not have mitogenic, polyclonal activity, antigenic properties, it does not have allergenic, mutagenic, embryotoxic, teratogenic and carcinogenic effects.

Azoximer bromide is odorless and tasteless, has no local irritant effect when applied to the mucous membranes of the nose and the oropharynx.

Pharmacokinetics

Azoximer bromide is characterized by rapid absorption and high distribution rate in the body. C_{max} of the drug in the blood with IM administration is achieved after 40 minutes. $T_{1/2}$ for different ages is from 36 to 65 hours. The bioavailability of the drug is high: more than 90% with parenteral administration. Azoximer bromide is rapidly distributed throughout all organs and tissues of the body, penetrates through the BBB and the blood-aqueous barrier. There is no cumulative effect. In the body, azoximer bromide undergoes biodegradation turning into low molecular oligomers, excreted mainly by the kidneys, with feces - not more than 3%.

Indications

Treatment and prevention of infectious and inflammatory diseases (viral, bacterial and fungal etiology) in the acute and remission stage in adults and children from 6 months.

Treatment of the following diseases and conditions of adults (in complex therapy):

- Chronic recurrent infectious and inflammatory diseases of various localization, bacterial, viral and fungal etiology in the acute stage;

- Acute viral, bacterial infections of ENT organs, upper and lower respiratory tract, gynecological and urological diseases;
- Acute and chronic allergic diseases (including pollinosis, bronchial asthma, atopic dermatitis), complicated by bacterial, viral and fungal infections;
- Malignant tumors, including the ones after chemo- and X-ray therapy for the reduction of the immunosuppressive, nephro- and hepatotoxic effects of drugs;
- Generalized forms of surgical infections;
- Activation of regenerative processes (fractures, burns, trophic ulcers);
- Rheumatoid arthritis, complicated by bacterial, viral and fungal infections in the setting of the prolonged use of immunosuppressants;
- Pulmonary tuberculosis.

Treatment of the following diseases and conditions in children older than 6 months (in complex therapy):

- Acute and aggravated chronic inflammatory diseases of any localization (including ENT organs - sinusitis, rhinitis, adenoiditis, pharyngeal tonsil hypertrophy, ARVI) caused by pathogens of bacterial, viral and fungal infections;
- Acute allergic and toxic-allergic conditions complicated by bacterial, viral and fungal infections;
- Bronchial asthma complicated by chronic respiratory tract infections;
- Atopic dermatitis complicated by the purulent infection;
- Intestinal dysbacteriosis (in combination with specific therapy).

Prevention of the following diseases and conditions (monotherapy) in children older than 6 months and adults:

- Flu and ARVI;
- Post-surgery infectious complications.

Contraindications

- Individual hypersensitivity;
- Acute renal insufficiency;
- Pregnancy;
- Lactation;
- Children under 6 months.

Precautions

Chronic renal failure (the drug must not be used more than 2 times a week).

Pregnancy and Lactation

The use of Polyoxidonium® by pregnant and breastfeeding women is contraindicated (clinical data is not available).

In the experimental study of Polyoxidonium® in animals, no effect on the generative function (fertility) of males and females has been recorded. Embryotoxic and teratogenic effects, effects on the development of the fetus, both during the drug administration throughout pregnancy and lactation, have not been recorded.

Side Effects

When using Polyoxidonium®, the following general and local reactions were recoded:

- Parenteral administration: infrequently (≥1 / 1000 to <1/100) - soreness, redness and skin induration at the injection site;
- Parenteral administration and local application: very rarely (≥1 / 10000) - fever, slight anxiety, chills, hypersensitivity to the components of the drug (allergic response).

Interaction with Other Drugs

Azoximer bromide does not inhibit the isoenzymes CYP1A2, CYP2C9, CYP2D9, CYP2D6 of cytochrome P450, therefore the drug is compatible with many medications, including antibiotic, antiviral, antifungal and antihistamine ones, GC and cytostatics.

Dosage and Administration

IV, IM, intranasal, sublingual administration.

Methods of administration, dosage regimen, necessity and frequency of the subsequent courses of therapy are determined by the doctor depending on the severity of the disease and the age of the patient.

Preparation of the solutions for the parenteral administration (IM and IV).

For the IM administration, 3 mg of Polyoxidonium® is dissolved in 1 ml (6 mg in 2 ml) of water for injection or a 0.9% of sodium chloride solution. After adding the solvent, the drug is left for 2–3 minutes to swell, and then it is mixed with rotational movements without shaking.

For the IV drop infusion, Polyoxidonium® is dissolved in 2 ml of sterile 0.9% sodium chloride solution. After adding the solvent, the drug is left for 2–3 min to swell, and then it is mixed with rotational movements. The dose calculated for the patient is poured in a sterile way into a vial / bag with a 0.9% sodium chloride solution. The solution prepared for the parenteral administration is not subject to storage.

Solution for Intranasal and Sublingual Administration.

For children, a dose of 3 mg is dissolved in 1 ml (20 drops), a dose of 6 mg in 2 ml (40 drops) (one drop (0.05 ml) of the prepared solution contains 0.15 mg of the drug); for adults, a dose of 6 mg is dissolved in 1 ml (20 drops) of distilled water or a 0.9% solution of sodium chloride or boiled water at indoor temperature.

Adults

IV, IM: the drug is prescribed to adults in doses of 6-12 mg once a day every day, every other day or 1-2 times a week, depending on the diagnosis and the severity of the disease.

Acute viral and bacterial infections of ENT organs, upper and lower respiratory tract, gynecological and urological diseases: 6 mg daily for 3 days, then every other day with a course of 10 injections.

Chronic recurrent infectious and inflammatory diseases of various localization of bacterial, viral and fungal etiology, in the acute stage: 6 mg every other day 5 injections, then 2 times a week with a course of 10 injections.

Acute and chronic allergic diseases (including pollinosis, bronchial asthma, and atopic dermatitis), complicated by bacterial, viral and fungal infections: 6-12 mg, 5 injections.

Rheumatoid arthritis, complicated by bacterial, viral and fungal infections, in the setting of prolonged use of immunosuppressants: 6 mg every other day 5 injections, then 2 times a week with a course of 10 injections.

Generalized forms of surgical infections: 6 mg daily for 3 days, then every other day with a course of 10 injections.

Activation of regenerative processes (fractures, burns, trophic ulcers): 6 mg for 3 days, then every other day, with a course of 10 injections.

Prevention of post-surgery infectious complications: 6 mg every other day, 5 injections.

Pulmonary tuberculosis: 6 mg 2 times a week with a course of 20 injections.

Cancer patients

- before and during the chemotherapy to reduce the immunosuppressive, hepato- and nephrotoxic effects of chemotherapeutic agents 6 mg every other day with a course of 10 injections; further, the frequency of administration is determined by the doctor, depending on the tolerance and duration of the chemo- and X-ray therapy;
- the long-term use (from 2–3 months to 1 year) of Polyoxidonium® is indicated for the prevention of the immunosuppressive effect of the tumor, for the correction of the immunodeficiency after the chemotherapy and X-ray therapy, after a surgical removal of the tumor, 6 mg 1-2 times a week. When prescribing a long-term course, the cumulating effects, toxicity and addiction are not observed.

The drug is prescribed for the intranasal administration at 6 mg/day (3 drops in each nasal passage 3 times a day, for 10 days) - for the treatment of acute and aggravated chronic infections of ENT organs; to strengthen regenerative processes of the mucous membranes; to prevent complications and relapses of chronic diseases; to prevent influenza and ARVI.

Children

Methods of administration are determined by the doctor depending on the severity of the disease and the age of the patient.

IV, IM, to children from 6 months in a dose of 0.1-0.15 mg/kg daily, every other day or 2 times a week with a course of 5-10 injections.

Intranasal and sublingual administration: daily, with a daily dose of 0.15 mg/kg with a course of up to 10 days. The drug is administered at 1-3 drops in one nasal passage or under the tongue with an interval of at least 1-2 hours, at 2-3 doses per day. One drop (0.05 ml) of the prepared solution contains 0.15 mg of the drug. The calculation of the daily dose for the intranasal and sublingual administration is presented in Table 1.

Table 1

Calculation of the daily dose of Polyoxidonium® for the intranasal or sublingual use in children

Body weight of the child, kg	Quantity, drops / day
5	5
10	10
15	15
20	20

If a child's body weight is more than 20 kg, the daily dose is calculated at the rate of 1 drop/kg, but not more than 40 drops (6 mg of active ingredient).

The solution prepared for the intranasal and sublingual administration can be stored at indoor temperature in the manufacturer's package for up to 48 hours.

Recommended treatment regimens in children.

IV, IM

Acute and aggravated chronic inflammatory diseases of any localization (including ENT organs - sinusitis, rhinitis, adenoiditis, pharyngeal tonsil hypertrophy, ARVI) caused by pathogens of bacterial, viral, fungal infections: 0.1 mg/kg for 3 days, then - every other day with a course of 10 injections.

Acute allergic and toxic-allergic conditions (including bronchial asthma, atopic dermatitis), complicated by bacterial, viral and fungal infection , IV by drop infusion in a dose of 0.1 mg/kg, 3 days daily, then every other day, with a course of 10 injections in combination with the baseline therapy.

Intranasal administration: daily, 1-2 drops in each nasal passage 3 times a day for up to 10 days (see Table 1) in case of acute and chronic rhinitis, rhinosinusitis, adenoiditis (treatment and prevention of acute conditions); for the pre-surgical preparation of patients in case of ENT pathology surgical interventions, as well as in the post-surgical period with the aim of preventing infectious complications or relapses of the disease; treatment and prevention of influenza and other ARVI (within 1 month before the expected epidemic), at any time after the onset of the disease and during convalescence period).

Sublingually, for children of early, preschool and primary school age: daily with a daily dose of 0.15 mg/kg in 2 divided doses for 10 days - in case of adenoiditis, tonsil hypertrophy: (as a component of the conservative treatment); for the pre-surgery preparation and post-surgery rehabilitation; as the seasonal prevention of exacerbations of chronic nidus of oropharynx and upper respiratory tract, inner and middle ear infections; treatment of intestinal dysbacteriosis (in combination with the baseline therapy) for 10 days.

Overdose

No cases of an overdose have been registered.

In case of an unintentional administration of a dosage exceeding the recommended one, please consult the doctor.

Precaution

If there is an allergic response in case of hypersensitivity to the drug's components, you should stop using the drug and consult the doctor.

If there is a need to stop taking the drug, cancellation can be done immediately, without a gradual dose reduction.

If you miss the administration of a next dose of the drug, its subsequent administration should be carried out as usual, as indicated in the description or recommended by the doctor. The patient should not administer a double dose to compensate for the missed ones.

The drug should not be used if there are visual signs of its unsuitability (packaging defect, powder color change).

In case of pain at the injection site, the drug is dissolved in 1 ml of a 0.5% solution of procaine (novocaine) if the patient does not have individual hypersensitivity to procaine (novocaine). In case of the IV (drip) administration the drug should not be dissolved in protein-containing infusion solutions.

Influence on the Ability to Drive Vehicles and Operate Mechanisms

The use of Polyoxidonium® does not affect the ability to perform potentially dangerous activities that require the increased concentration of attention and the speed of psychomotor reactions (including driving and working with moving mechanisms).

Drug Form

Lyophilisate for a solution for injections and local administration, 3 mg, 6 mg.

4.5 mg of the drug (for a dosage of 3 mg) or 9 mg of the drug (for a dosage of 6 mg) in glass vials of hydrolytic class I, hermetically sealed with rubber stoppers and rolled with aluminum caps.

5 vials with the drug in a blister strip packaging made of PVC film.

One blister strip pack is placed in a cardboard package or 5 vials are placed in a cardboard package with a cardboard insert. 50 vials (for in-patient hospitals) with the drug are placed in a box with cardboard partitions.

Manufacturer

NPO Petrovax Pharm, LLC

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Storage Conditions of Polyoxidonium®

At a temperature of 2–8°C. Keep out of the reach of children.

Shelf Life of Polyoxidonium®

3 years.