THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

PATIENT INFORMATION LEAFLET FOR THE DRUG PRODUCT POLYOXIDONIUM®

Please read carefully this leaflet before starting use this medicinal product, since it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have further questions, consult your doctor.

This drug is over the counter. To achieve relevant results, it should be used following strictly all guidance outlined in this instruction.

This medicinal product is prescribed personally for you, and you should not deliver it to another persons, because it can be damaging for them even in the presence of the same symptoms as you have.

Registration number: P N002935/03

Trade name: Polyoxidonium®

International Nonproprietary Name: Azoximer bromide (Azoximeri bromidum)

Chemical name: copolymer of N-oxide of 1,4-ethylene piperazine and (N-carboxymethyl)-1,4-ethylene piperazinium bromide

Dosage form: vaginal and rectal suppositories

Composition per suppository:

Active substance: azoximer bromide - 6 mg or 12 mg;

Excipients:

mannitol - 1.8 mg, povidone - 1.2 mg, cocoa seed butter (cocoa butter) – 1291,0 mg (for 6 mg dosage);

mannitol – 3.6 mg, povidone – 2.4 mg, cocoa seed butter (cocoa butter) – 1282.0 mg (for 12 mg dosage).

Description: light yellow torpedo-shaped suppositories, with mild specific cocoa butter odor.

Suppositories should be homogenous. On the section, the presence of an air stem or funnel-like recession is permitted.

Pharmacotherapeutic group: immunomodulatory agent.

ATC code: [L03]

Pharmacological properties

Pharmacodynamics

Azoximer bromide has combined immune-modulating, detoxifying, antioxidant, and moderate anti-inflammatory effects.

The immune-modulating effect of Azoximer bromide is based on its direct influence on phagocytic cells and natural killer cells, as well as its ability to stimulate antibody production and interferon-alpha and interferon-gamma synthesis.

Detoxifying and antioxidant effects of Azoximer bromide are mostly attributed to its structure and high-molecular nature.

Azoximer bromide strengthens the body's resistance to local and generalized bacterial, fungal and viral infections. It restores immune functions in patients with secondary immune deficiencies caused by various infections, traumas, surgical complications, burns, autoimmune diseases, malignant neoplasms, or the use of chemotherapeutic agents, cytostatics or steroid hormones.

Azoximer bromide blocks soluble toxic substances and microparticles, removes toxins and salts of heavy metals, inhibits lipid peroxidation by seizing free radicals and eliminating catalytically active bivalent Fe^{2+} ions. Azoximer bromide reduces the inflammatory response by optimizing the synthesis of pro-and anti-inflammatory cytokines.

Azoximer bromide is well-tolerated, shows no mitogenic or polyclonal activity, and has no antigen properties. The medicine has no allergenic, mutagenic, embryotoxic, teratogenic or carcinogenic effects.

Pharmacokinetics

Azoximer bromide in suppositories after rectal administration has high bioavailability (not less than 70 %), achieving the maximal plasma concentration within 1 hour after administration. The half-life time is about 0.5 hour, the elimination half-life is about 36.2 hours. It hydrolyzes to oligomers in the body which major elimination route is via the kidneys. The medicine has no cumulative effect.

Indications

It is used for the treatment and prevention of infectious and inflammatory diseases (of viral, bacterial, and fungal etiology), in the exacerbation and remission stages in adults and children over 1 year old.

For the treatment of adults (in the combined therapy):

- Acute diseases and exacerbated chronic recurrent infectious and inflammatory diseases of various localizations, of bacterial, viral, and fungal etiology;

- inflammatory diseases of the urogenital tract (urethritis, cystitis, pyelonephritis, prostatitis, adnexitis, endometritis, colpitis, cervicitis, cervicosis, and bacterial vaginosis);
- different pulmonary tuberculosis forms;
- allergic diseases (including pollinosis, bronchial asthma, atopic dermatitis) complicated by recurrent bacterial fungal and viral infections;
- rheumatoid arthritis complicated by recurrent bacterial, fungal, and viral infection, against a background of long-term immunosuppressant treatment;
- to activate regenerative processes (fractures, burns, and trophic ulcers);
- in the combined therapy of cancer during chemotherapy and radiotherapy, to reduce the nephro- and hepatotoxic effects of drug products.

For prevention in adults (monotherapy):

- recurrent and herpetic infections of the urogenital tract;
- in exacerbated chronic infection foci;
- Influenza and other acute respiratory infections in the pre-epidemic and epidemic period in immunocompromised individuals;
- secondary immunodeficiencies resulting from ageing or exposure to adverse factors.

For the treatment of children aged 6 to 18 (in the combined therapy):

- Acute diseases and exacerbated chronic recurrent infectious and inflammatory diseases of various localizations, of bacterial, viral, and fungal etiology;
- inflammatory diseases of the urogenital tract (urethritis, cystitis, and pyelonephritis);
- different pulmonary tuberculosis forms;
- allergic diseases (including pollinosis, bronchial asthma, atopic dermatitis) complicated by recurrent bacterial fungal and viral infections;
- to activate regenerative processes (fractures, burns, and trophic ulcers);
- in the combined therapy of cancer during chemotherapy and radiotherapy, to reduce the nephro- and hepatotoxic effects of drug products.

For prevention in children aged 6 to 18 (monotherapy):

- recurrent and herpetic infections of the urogenital tract;
- in exacerbated chronic infection foci;

- Influenza and other acute respiratory infections in the pre-epidemic and epidemic period in immunocompromised individuals.

For the treatment of children aged 1 to 6 (in the combined therapy):

- Acute diseases and exacerbated chronic recurrent infectious and inflammatory diseases of various localizations, of bacterial, viral, and fungal etiology;
- inflammatory diseases of the urogenital tract (urethritis, cystitis, and pyelonephritis);
- different pulmonary tuberculosis forms;
- allergic diseases (including pollinosis, bronchial asthma, atopic dermatitis) complicated by recurrent bacterial fungal and viral infections;
- to activate regenerative processes (fractures, burns, and trophic ulcers).

For prevention in children aged 1 to 6 (monotherapy):

- recurrent and herpetic infections of the urogenital tract;
- in exacerbated chronic infection foci;
- Influenza and other acute respiratory infections in the pre-epidemic and epidemic period in immunocompromised individuals.

Contraindications

- Hypersensitivity to azoximer bromide or any of the excipients of the drug product;
- pregnancy, breast-feeding period;
- pediatric patients under 1 year of age;
- acute renal failure.

With caution

If you have any of the conditions listed in this section, consult your doctor before taking this medicine:

- chronic renal failure (prescribe not more than twice a week).

Use in pregnancy and breast-feeding period

The use is contraindicated in pregnant and breast-feeding women (no clinical experience of use).
During the experimental study of Polyoxidonium® in animals, no embryotoxic, teratogenic effects, or effects on fetal development were revealed.
If you are pregnant or suppose pregnancy, or are planning pregnancy, you must consult your doctor before use of Polyoxidonium®.
In the breast-feeding period, you should consult your doctor before use of Polyoxidonium®.

Method of administration and dosage

Only use the drug product according to the indication, the method of administration, and the dosage indicated in the instructions.

If there is no improvement after treatment, or if symptoms worsen or new symptoms appear, please consult your doctor.

If necessary, repeated therapy courses may be performed after 3-4 months. No reduction in the drug efficacy if repeatedly administered.

Recommended treatment regimens

Adult use

– 1 suppository rectally once a day after bowel evacuation;

– vaginally for gynaecological diseases: insert 1 suppository once a day (at night) into the vagina in a supine position.

For treatment of adults:

- in exacerbated chronic inflammatory and infectious diseases – 12 mg suppositories once a day for 3 days, then on alternate days. Treatment course – 10 suppositories;
- in acute infections and to activate regenerative processes (fractures, burns, trophic ulcers) – 12 mg suppositories once a day. Treatment course – 10 suppositories;
- in gynecological diseases – 12 mg suppositories once a day for 3 days, then on alternate days. Treatment course – 10 suppositories;
- in exacerbated urological diseases (urethritis, cystitis, pyelonephritis, and prostatitis) – 12 mg suppositories once a day. Treatment course – 10 suppositories;
- in pulmonary tuberculosis – 12 mg suppositories once a day for 3 days, then on alternate days. Treatment course – 20 suppositories. Further supportive therapy with 6 mg suppositories twice a week can be used as a course of up to 2-3 months;
- in the combined therapy of cancer during chemotherapy and radiotherapy – 12 mg suppositories once a day 2-3 days before chemotherapy or radiotherapy. Then 12 mg twice a week, as a course of up to 20 suppositories;
- in allergic diseases complicated by an infection syndrome – 12 mg suppositories once a day. Treatment course – 10 suppositories;
- in rheumatoid arthritis – 12 mg suppositories on alternate days. Treatment course – 10 suppositories.

For prevention (monotherapy):

- in exacerbated chronic infection foci, recurrent herpetic urogenital infection – 12 mg suppositories on alternate days. Treatment course – 10 suppositories;
- influenza and ARVI – 12 mg suppositories once a day. Treatment course – 10 suppositories;
- secondary immune deficiencies occurred due to aging – 12 mg suppositories twice a week. Treatment course – 10 suppositories, 2–3 times annually.

Paediatric use

For children and adolescents aged 1 to 18, the suppositories are only rectally administered, 1 6 mg suppository once a day after bowel evacuation.

For the treatment in children and adolescents aged 6 to 18:

- in exacerbated chronic inflammatory diseases – 6 mg suppositories once a day for 3 days, then on alternate days. Treatment course – 10 suppositories;
- in acute infection processes and for regeneration processes' activation (fractures, burns, trophic ulcers) – 6 mg suppositories once a day. Treatment course – 10 suppositories;
- in exacerbated urological diseases (urethritis, cystitis, pyelonephritis, prostatitis) – 6 mg suppositories once a day. Treatment course – 10 suppositories;
- in pulmonary tuberculosis – 6 mg suppositories once a day for 3 days, then on alternate days. Treatment course – 20 suppositories. Further the supporting therapy is possible by 6 mg suppositories twice a week, as course of up to 2–3 months;
- in the combined therapy of cancer during chemotherapy and radiotherapy – 6 mg suppositories once a day 2-3 days before chemotherapy or radiotherapy. Then 6 mg 2 times a week, as a course of up to 20 suppositories;
- in allergic diseases complicated with infection syndrome – 6 mg suppositories once a day. Treatment course – 10 suppositories;

For prevention in children and adolescents aged 6 to 18 (monotherapy):

- in exacerbated chronic infection foci, recurrent herpetic urogenital infection – 6 mg suppositories on alternate days. Treatment course – 10 suppositories;
- influenza and ARVI – 6 mg suppositories once a day. Treatment course – 10 suppositories.

For treatment in children aged 1 to 6:

- in exacerbated chronic infectious and inflammatory diseases — 6 mg suppositories once a day with the first three intakes every day, then increase the interval between the administrations to 3 days. Treatment course – 5 suppositories;

- in acute infection processes and for regeneration processes' activation (fractures, burns, trophic ulcers) – 6 mg suppositories once a day on alternate days. Treatment course – 5 suppositories;
- in exacerbated urological diseases (urethritis, cystitis, pyelonephritis, prostatitis) – 6 mg suppositories once a day on alternate days. Treatment course – 5 suppositories;
- in pulmonary tuberculosis - 6 mg suppositories once a day for the first three administrations on alternate days, then the interval is increased to 3 days. Treatment course – 10 suppositories;
- in allergic diseases complicated with infection syndrome – 6 mg suppositories once a day on alternate days. Treatment course – 5 suppositories.

For prevention in children aged 1 to 6 (monotherapy):

- in exacerbated chronic infection foci, recurrent herpetic urogenital infection – 6 mg suppositories once a day with an interval of 3 days. Treatment course – 5 suppositories;
- influenza and ARVI – 6 mg suppositories once a day on alternate days. Treatment course – 5 suppositories.

The prolonged 2–3 months- to one-year supporting therapy with Polyoxidonium® (adults 12 mg, children over 6 years – 6 mg 1–2 times a week) is indicated for patients on prolonged immunosuppressive therapy, cancer patients receiving radiotherapy, patients with the acquired immune deficiency syndrome – HIV.

Side effects

Very rare: local reactions such as erythema, swelling, perianal pruritus, vaginal pruritus associated with individual sensitivity to medicinal product components.

Please inform your doctor if you noticed any side effects not stated in the instruction.

Overdose

No cases of overdose have been reported.

Drug-to-drug interactions

Azoximer bromide does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2D6 isoenzymes of the P-450 cytochrome, therefore the drug product is compatible with many other drugs, including antibiotics, antiviral, antifungal drugs and antihistamines, glucocorticosteroids, and cytostatic agents.

If you are taking any of the above or other drug products (including over-the-counter pharmaceuticals), consult your doctor before starting to use Polyoxidonium®.

Special instructions

If an allergic reaction develops, you should stop using Polyoxidonium® and consult a doctor.

If you need to stop taking Polyoxidonium®, you can cancel it immediately. If the single dose is missed, you should take it as early as possible but if the time for the next dose occur; do not increase the dose.

Do not use the medicinal product if there are visual signs of its unsuitability (a packaging defect, discoloration of the suppository).

Effects on ability to drive and use mechanisms

The use of Polyoxidonium® does not affect the ability to drive, operate moving mechanisms and perform other types of activities that require increased concentration of attention and speed of psychomotor reactions.

Presentation

Vaginal and rectal suppositories, 6 mg, 12 mg.

5 suppositories in contour cell package made of polyvinyl chloride film. 2 contour cell packages with package insert are placed in a carton pack.

Expiry date

2 years. Do not use medicinal product after expiry date.

Storage conditions

Store below 15 ºC.

Do not freeze. Keep out of reach of children.

Pharmacy purchasing terms

Over the counter.

Manufacturer (batch release)/Legal entity in whose name the marketing authorization is issued

NPO Petrovax Pharm LLC

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Organization that accepts claims from consumers

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