## THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

## PATIENT INFORMATION LEAFLET

## FOR THE DRUG PRODUCT POLYOXIDONIUM®

Read the leaflet carefully before you start using this medicine because it contains important information for you.

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

If you have any further questions, ask your doctor.

This is an OTC drug. To get the maximum effect, you should strictly follow the recommendations provided in this leaflet.

This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

**Registration number:** P N002935/03

**Trade name:** Polyoxidonium®

**International non-proprietary name:** Azoximer bromide (Azoximeri bromidum)

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

**Form of medicine:** vaginal and rectal suppositories

###### Each suppository contains:

Active substance: Azoximer bromide – 6 mg or 12 mg;

Excipients:

mannitol – 1.8 mg, povidone K17 – 1.2 mg, cocoa butter – 1,291.0 mg (for 6 mg dosage),

mannitol – 3.6 mg, povidone K17 – 2.4 mg, cocoa butter – 1,282.0 mg (for 12 mg dosage),

**Description:** light-yellow torpedo-shaped suppositories with a faint characteristic odor of cocoa butter.

Suppositories must be homogeneous. An air column or a funnel-shaped hollow may be present on a cut surface.

**Pharmacotherapeutic group:** immune-modulating drug

**ATC code:** [L0З]

**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 IFN-alpha and IFN-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 ferrum 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 when administered rectally has a high bioavailability (not less than 70%), reaching the peak blood concentration after 1 hour since the administration. The alpha half-life is about 0.5 hours, the half-life is 36.2 hours. Within the body, it is hydrolyzed to oligomers mainly excreted by the kidneys. The medicine has no cumulative effect.

**Indications for use**

Azoximer bromide is used for the treatment and prophylaxis of infectious and inflammatory diseases (of viral, bacterial or fungal etiology) in adults and children over 6 years old. The medicine is effective in the acute phase of a disease and during the remission.

For treatment (combined therapy):

* acute and exacerbated chronic recurrent infectious and inflammatory diseases of various localization, bacterial, viral or fungal etiology;
* inflammatory diseases of the urogenital tract (urethritis, cystitis, pyelonephritis, prostatitis, salpingo-oophoritis, endomyometritis, colpitis, cervicitis, cervicosis, bacterial vaginosis);
* various forms of pulmonary tuberculosis;
* allergic diseases (including pollinosis, bronchial asthma, atopic dermatitis) complicated by recurrent bacterial, viral or fungal infections;
* rheumatoid arthritis complicated by recurrent bacterial, viral or fungal infections associated with the prolonged use of immunosuppressants;
* for the activation of regenerative processes (to treat fractures, burns, trophic ulcers);
* in the combined therapy of oncological diseases using chemotherapy or X-ray therapy, to reduce nephro- and hepatotoxic effects of these medicinal products.

For prophylaxis (monotherapy):

* recurrent herpes infection of the urogenital tract;
* exacerbations of chronic foci of infections;
* influenza and other acute respiratory infections in immunocompromised persons in the pre-epidemic or epidemic period;
* secondary immune deficiencies caused by ageing or adverse factors.

**Contraindications**

* increased individual sensitivity;
* pregnancy, breast-feeding;
* children aged under 6 years old;
* acute renal failure.

**Warnings and precautions**

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

* chronic renal failure (use no more than twice a week).

**Use in pregnancy and breast-feeding period**

The use of this medicinal product is contraindicated in pregnant and breast-feeding women (no clinical experience of use).

During the experimental use of Polyoxidonium® in animals, no embryotoxic, teratogenic, or fetal development effects were revealed.

Please consult your doctor before using Polyoxidonium® if you are, suspect that you could be, or plan to become pregnant.

During breast-feeding, consult your doctor before using Polyoxidonium®.

**Dosage and administration**

Use the medicinal product only in accordance with the indications, the route of administration and the doses indicated in the leaflet.

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

Use the drug rectally or vaginally once daily (every day or every other day or twice a week).

If necessary, repeated courses of therapy are possible after 3–4 months. The efficacy of the medicinal product does not decrease when represcribed.

*Recommended treatment regimen*

For treatment in adults:

– 1 suppository rectally once daily after bowel cleansing;

– to treat a gynecological disease, insert 1 suppository once daily (before night sleep) into the vagina while in the prone position.

* chronic infectious and inflammatory diseases in the acute stage – 12 mg suppositories once daily for 3 days, then every other day. A total of 10 suppositories;
* acute infectious processes or to activate regenerative processes (to treat fractures, burns, trophic ulcers) – 12 mg suppositories once daily. A total of 10 suppositories;
* pulmonary tuberculosis – 12 mg suppositories once daily for 3 days, then every other day. A total of 10 suppositories;
* exacerbations of urological diseases (urethritis, pyelonephritis, cystitis, prostatitis) – 12 mg suppositories once daily. A total of 10 suppositories;
* pulmonary tuberculosis – 12 mg suppositories once daily for 3 days, then every other day. A total of 20 suppositories. From then on, it is possible to use maintenance therapy with 6 mg suppositories twice a week for 2–3 months;
* in the combined therapy of oncological diseases using chemotherapy or X-ray therapy – 12 mg suppositories daily for 2–3 days before the start of a chemotherapy or X-ray therapy course. From then on, 12 mg twice a week (a total of up to
20 suppositories);
* allergic diseases complicated by an infectious syndrome – 12 mg suppositories once daily. A total of 10 suppositories;
* rheumatoid arthritis – 12 mg suppositories every other day. A total of 10 suppositories.

For prophylaxis (monotherapy):

* exacerbations of chronic foci of infections, a recurrent herpes infection of the urogenital tract – 12 mg suppositories every other day.
A total of 10 suppositories;
* influenza and ARVI – 12 mg suppositories once daily. A total of 10 suppositories;
* secondary immune deficiencies caused by ageing – 12 mg suppositories twice a week. A total of 10 suppositories 2–3 times a year.

For treatment in children and adolescents between 6 and 18 years old:

For children and adolescents between 6 and 18 years old, suppositories are only administered rectally, one 6 mg suppository once daily after bowel cleansing.

* chronic infectious and inflammatory diseases in the acute stage – 6 mg suppositories once daily for 3 days, then every other day. A total of 10 suppositories;
* acute infectious processes or to activate regenerative processes (to treat fractures, burns, trophic ulcers) – 6 mg suppositories once daily. A total of 10 suppositories;
* exacerbations of urological diseases (urethritis, pyelonephritis, cystitis, prostatitis) – 6 mg suppositories once daily. A total of 10 suppositories;
* pulmonary tuberculosis – 6 mg suppositories once daily for 3 days, then every other day. A total of 20 suppositories. From then on, it is possible to use maintenance therapy with 6 mg suppositories twice a week for 2–3 months;
* in the combined therapy of oncological diseases using chemotherapy or X-ray therapy – 6 mg suppositories daily for 2–3 days before the start of a chemotherapy or X-ray therapy course. From then on, 6 mg twice a week (a total of up to 20 suppositories);
* allergic diseases complicated by an infectious syndrome – 6 mg suppositories once daily. A total of 10 suppositories;
* rheumatoid arthritis – 6 mg suppositories every other day. A total of 10 suppositories.

For prophylaxis (monotherapy):

* exacerbations of chronic foci of infections, a recurrent herpes infection of the urogenital tract – 6 mg suppositories every other day.
A total of 10 suppositories;
* influenza and ARVI – 6 mg suppositories once daily. A total of 10 suppositories.

For patients on long-term immunosuppressive therapy, cancer patients, those having been exposed to radiation or with an acquired deficiency of the immune system – HIV, long-term maintenance Polyoxidonium therapy between 2–3 months and 1 year is indicated (12 mg for adults, 6 mg for children over 6 years old, 1–2 times a week).

**Side effects**

Very rare: local reactions in the form of redness, edema, itching of the perianal area, vaginal itching due to individual sensitivity to product components.

If you notice any side effects not listed in the leaflet, please notify your doctor.

**Overdose**

No cases of overdose have been reported.

**Drug interactions**

Azoximer bromide does not inhibit cytochrome P-450 isoenzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6; therefore, the medicinal product is compatible with many medications, including antibiotics, antiviral, antifungal and antihistamine agents, glucocorticosteroids, and cytostatics.

If you are taking any of the above or other medicinal products (including over-the-counter medications), please consult your doctor before taking 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 a single dose of the medicinal product is missed, it is necessary to take it as early as possible, but if it is time to take the next dose, do not increase it.

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 machines**

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

**Dosage form**

Vaginal and rectal suppositories, 6 mg, 12 mg.

5 suppositories in a blister pack made of polyvinyl chloride film. Two blister packs together with the package leaflet placed in a carton.

**Shelf life**

2 years. Do not use after expiration date.

**Storage conditions**

Store in a dry place at 2–15оС.

Keep out of reach of children.

**Pharmacy purchasing terms**

Over the counter.

**Manufacturer / marketing authorization holder**

Marketing authorization holder, and manufacturer:

NPO Petrovax Pharm LLC

Registered office / address for customer complaints: 1 Sosnovaya St., Pokrov village, Podolsk, Moscow Region, 142143, Russia, tel./fax: +7 495 926 2107, e-mail: info@petrovax.ru;

For complaints: tel.: +7 495 730 2107, e-mail: adr@petrovax.ru;

Manufacture / prepackaging (primary packaging):

10 Zagoryevskaya Str, Bld. 4, Moscow, 115598, Russia , tel./fax: +7 495 329 1718.

Secondary (consumer) packaging / release quality control:

1 Sosnovaya St., Pokrov village, Podolsk, Moscow Region, 142143, Russia, tel./fax: +7 495 926 2107.