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 N002935/04

Trade name: Polyoxidonium®

International Nonproprietary Name: Azoximer bromide (Azoximeri bromidum)

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

Pharmaceutical form: tablets

Each tablet contains:

Active substance: azoximer bromide – 12 mg;

Excipients: mannitol – 3.6 mg, povidone – 2.4 mg, lactose monohydrate – 185.0 mg, potato starch – 45.0 mg, stearic acid – 2.0 mg.

Description: circular planocylindrical beveled edge tablets white to off-white in colour, with a break line on the one side and "ПО" debossing on the other side.

Pharmacotheraupeutic group: immune-modulating drug

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 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 generalised bacterial, fungal and viral infections. It restores immune functions in patients with secondary immune deficiencies caused by various infections, traumas and surgical complications.

Local (sublingual) administration of Azoximer bromide activates rapid immune response to infections: the medicine enhances bactericidal properties of neutrophils and macrophages, amplifies their ability to engulf bacteria, and strengthens bactericidal properties of the saliva and upper respiratory tract secretions.

Oral administration of Azoximer bromide also activates lymphoid cells in the lymph nodes of the intestine.

Azoximer bromide blocks soluble toxic substances and microparticles, removes toxins and salts of heavy metals, inhibits lipid peroxidation by seizing free radicals and by eliminating catalytically active bivalent ferrum ions. Azoximer bromide reduces the inflammatory response by optimising 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.

Azoximer bromide has no smell or taste, and does not irritate nasal and oral mucosae.

Pharmacokinetics

After the ingestion, the medicine is rapidly absorbed from the gastro-intestinal tract. The bioavailability of Azoximer bromide administered orally exceeds 70%. The peak plasma concentration is attained after 3 hours since the administration. The pharmacokinetics of Azoximer bromide is linear (the plasma concentration is proportional to the dose taken).

Azoximer bromide is a hydrophilic composition. The apparent volume of distribution is approximately 0.5 L/kg, which proves that the medicine is distributed mostly in the intercellular fluid. The absorption half-life is 35 minutes, and the elimination half-life is 18 hours.

Azoximer bromide is distributed fast to all organs and tissues, and passes through the blood-brain and blood-ocular barriers. The medicine has no cumulative effect. Azoximer bromide is eliminated to low-molecular oligomers, the major elimination route is via kidneys, via faeces not more than 3%.-

Indications for use

Azoximer bromide is used for the treatment and prophylaxis of acute and chronic respiratory infections in adults and children aged 3+. The medicine is effective in the acute phase of a disease and during the remission.

For treatment (combined therapy) of:

- acute and chronic recurrent inflammatory infections of the mouth and throat, paranasal sinuses, upper and lower respiratory tract, inner and middle ear;
- allergic diseases (including pollinosis and bronchial asthma) complicated by recurrent bacterial, fungal or viral infections;

For prophylaxis (monotherapy) of:

- recurrent herpetic infection of the nasal and labial zones;
- relapses of the chronic nidi of infections in the mouth and throat, paranasal sinuses, upper respiratory tract, inner and middle ear;
- secondary immune deficiencies caused by ageing or adverse factors.

Contraindications

- individual drug sensitivity;
- pregnancy, breastfeeding;
- children age under 3 years;
- acute kidney injury;
- rare congenital lactase intolerance, lactase deficiency, glucose-galactose malabsorption.

Warnings and precautions

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

– chronic kidney injury (use no more than twice a week).

Use in pregnancy and lactation

The use of Polyoxidonium® 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 pregnant, suspect that you could be pregnant, or plan to become pregnant.

During lactation, 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 instructions.

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

Orally and sublingually 20–30 minutes before meals twice daily: children over 10 years old and adults – 1 tablet, children between 3 and 10 years old – ½ tablet (6 mg).

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

Sublingually

For adults to treat:

- influenza and acute respiratory infections – 1 tablet twice daily for 7 days;
- inflammatory processes of mouth and throat – 1 tablet twice daily for 10 days;
- exacerbations of chronic diseases of the upper respiratory tract, paranasal sinuses, chronic otitis – 1 tablet twice daily for 10 days;
- allergic diseases (including pollinosis, bronchial asthma) complicated by recurrent bacterial, fungal and viral infections – 1 tablet twice daily for 10 days.

For children between 3 and 10 years old to treat:

- influenza and acute respiratory infections – ½ tablet twice daily for 7 days;
- inflammatory processes of mouth and throat – ½ tablet twice daily for 7 days;

- allergic diseases (including pollinosis, bronchial asthma) complicated by recurrent bacterial, fungal and viral infections – ½ tablet twice daily for 7 days.

For children over 10 years old to treat:

- influenza and acute respiratory infections – 1 tablet twice daily for 7 days;
- inflammatory processes of mouth and throat – 1 tablet twice daily for 7 days;
- exacerbations of chronic diseases of the upper respiratory tract, paranasal sinuses, chronic otitis – 1 tablet twice daily for 7 days;
- allergic diseases (including pollinosis, bronchial asthma) complicated by recurrent bacterial, fungal and viral infections – 1 tablet twice daily for 7 days.

For adults to prevent:

- influenza and acute respiratory infections in the pre-epidemic period – 1 tablet daily for 10 days;
- recurrent herpes infection of the nasal and labial area – 1 tablet twice daily for 10 days;
- exacerbations of chronic nodi of infections of mouth and throat, paranasal sinuses, upper respiratory tract, inner and middle ear – 1 tablet once daily for 10 days;
- secondary immune deficiencies caused by ageing or adverse factors – 1 tablet once daily for 10 days;.

For children between 3 and 10 years old to prevent:

- influenza and acute respiratory infections in the pre-epidemic period – ½ tablet daily for 7 days;
- recurrent herpes infection of the nasal and labial area – ½ tablet twice daily for 7 days;
- exacerbations of chronic nodi of infections of mouth and throat, paranasal sinuses, upper respiratory tract, inner and middle ear – ½ tablet once daily for 10 days.

Children over 10 years old to prevent:

- influenza and acute respiratory infections in the pre-epidemic period – 1 tablet daily for 7 days;
- recurrent herpes infection of the nasal and labial area – 1 tablet twice daily for 7 days;
- exacerbations of chronic foci of infections of mouth and throat, paranasal sinuses, upper respiratory tract, inner and middle ear – 1 tablet once daily for 10 days.

Orally

For adults to treat:

- diseases of the upper and lower respiratory tract – 1 tablet twice for 10 days.

For children over 10 years old to treat:

- diseases of the upper and lower respiratory tract – 1 tablet twice for 10 days.

Side effects

No side effects have been reported.

If you notice any side effects not listed in the instructions, 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 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, without a gradual dose reduction.

If the next dose of the medicinal product is missed, you should continue to use it as usual, in line with these instructions or a doctor's recommendations. Do not take a double dose to compensate for the missed ones.

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

Effects on ability to drive and use machines

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

Dosage form

Tablets, 12 mg.

10 tablets in a blister pack made of polyvinyl chloride film and aluminium foil. One or two blisters together with the instructions for use packaged in a carton box.

Shelf life

3 years. Do not use after expiration date.

Storage conditions

Store at temperature less than 25°C. Keep out of reach of children.

Pharmacy purchasing terms

Over the counter.

Manufacturer (release quality control) / Marketing authorisation holder

NPO Petrovax Pharm LLC

1 Sosnovaya St., Pokrov village, Podolsk, Moscow Region, 142143, Russia

Organization that receives claims from consumers

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