

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Lysobact[®] compressed lozenges

INN: Lysozyme hydrochloride, pyridoxine hydrochloride.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lysobact compressed lozenge contains:

Active ingredient: Lysozyme hydrochloride	20.00 mg
Pyridoxine hydrochloride	10.00 mg

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Compressed lozenges white to off white in color, round in shape, with flat and smooth surfaces, and undamaged edges with an embossed break-mark on one side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

LYSOBACT is indicated for the treatment of infectious-inflammatory diseases of the oral, gingival, and laryngeal mucous membrane: gingivitis, stomatitis, acute upper respiratory tract infections at multiple or unspecified sites (acute laryngopharyngitis, other acute upper respiratory tract infections at multiple sites, unspecified acute upper respiratory tract infection), aphthous ulcers, herpetic lesions (as part of a complex therapy regimen), and erosion of the oral mucosa of any origin.

4.2. Posology and method of administration

The product is for topical administration. The compressed lozenges should be slowly dispersed in the mouth without chewing, the melting substance of the compressed lozenge should be retained in the mouth as long as possible, until complete dissolution. For children aged 7 to 12 years: one compressed lozenge four times per day. For adults and children over 12 years of age: 2 compressed lozenges three or four times per day. A treatment course should last 8 days (or longer if necessary).

4.3. Contraindications

- Hypersensitivity to any component of the medicinal product (including the egg white allergy)
- Age under 7 years
- Hereditary lactose intolerance; lactase deficiency or glucose - galactose malabsorption.

4.4. Special warnings and special precautions for use

In the event of an allergic reaction, the drug should be immediately discontinued and a physician consulted.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. essentially "sodium free".

4.5. Interaction with other medicaments and other forms of interaction

- Lysozyme augments the effects of antibiotics, including penicillin, chloramphenicol, and nitrofurantoin.
- Estrogen, estrogen containing contraceptives increase the need for pyridoxine
- Levodopa - weakening of anti-Parkinsonian activity, pyridoxine accelerates decarboxylation of levodopa (does not reduce the effect of the combination of levodopa + carbidopa).
- Diuretics in the combined use with pyridoxine amplifies the effect of diuretics.
- Pyridoxine prevents or reduces the toxic manifestation of isoniazid, including liver damage observed in the application of isoniazid and other anti-TB drugs.
- Penicillamine, pyrazinamide, immunosuppressants while the use of pyridoxine reduces effect of the latter.

4.6. Pregnancy and breastfeeding

The experience of clinical use, associated with the effect of the drug on fetus, is inadequate. As a precaution measure, this medicine is not recommended for usage during pregnancy. Since there is not enough data on the excretion into breast milk, the medicine should not be used during breastfeeding.

4.7. Effect on ability to drive and use machines

The medication has no effect on the ability to drive or to operate mechanisms.

4.8. Undesirable effects

The medicinal product is usually well tolerated, and adverse reactions are rarely observed. Allergic reactions may occur in some cases.

Disorders at the level of skin and subcutaneous tissue: urticaria, pruritus, photosensitivity.

4.9. Overdose

No cases of acute overdose with Lysobact have been reported.

Administration of high pyridoxine doses significantly exceeding the therapeutic level (> 200 mg/day) over a long period of time (months or years) may cause symptoms of sensory

neuropathy manifested by numbness and tingling sensations, as well as loss of sensation in the upper and lower extremities. These symptoms are reversible and resolve spontaneously after discontinuation of treatment.

Treatment: discontinuation of the medicinal product, abundant oral fluid intake (forced diuresis).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: antiseptic agents.

ATC code: R02AA20.

Combination drug whose action is due to the effects of its constituent components.

Lysozyme is a protein enzyme that is used as an antiseptic. Lysozyme causes lysis of the cell wall in Gram-positive and Gram-negative bacteria, as well as in fungi. It displays an antiviral activity. Lysozyme plays a role in the regulation of local non-specific immunity. Lysozyme is a natural protective factor of the human body.

Pyridoxine has a protective effect on the oral mucous membrane (thus exerting an anti-apthous effect). It does not affect the pharmacodynamic properties of lysozyme.

5.2. Pharmacokinetic properties

Absorption of Lysobact commences in the mouth. It is well distributed in the organism, it is especially concentrated in mucosas, and it is excreted in the form of metabolites. Pyridoxine crosses placental barrier and it is excreted in mother's milk. It is excreted via urine in the form of 4-pyridoxic acid.

5.3. Preclinical safety data

Preclinical details do not show a special risk for people on the basis of conventional tests of safety pharmacology, multiple doses toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

- Lactose Monohydrate
- Hypromellose
- Magnesium Stearate
- Saccharin Sodium
- Vanillin

6.2. Incompatibilities

No data on incompatibility have been reported.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

Store at temperature below 30 °C.

6.5. Nature and contents of container

10 compressed lozenges in a PVC/aluminum foil blister strip.

1 or 3 blister strips per carton, along with a copy of the Prescribing Information.

6.6. Instructions for usage and handling and special precautions for disposing of the unused medicines or their waste

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.7. Issuing regime

Without a medical prescription, in pharmacy.

7. MARKETING AUTHORISATION HOLDER

Bosnalijek, Limited Liability Company, Savvinskaya naberezhnaya 11, Moscow, Russian Federation

8. MARKETING AUTORISATION CLASS AND NUMBER**10. TEXT REVISION DATE**

September 2025.