

PACKAGE LEAFLET: INFORMATION FOR THE USER

LYSOBACT

20 mg / 10 mg, compressed lozenges

LYSOZYME / PYRIDOXINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What LYSOBACT compressed lozenges is and what it is used for
2. Before you take LYSOBACT
3. How to take use LYSOBACT
4. Possible side effects
5. How to store LYSOBACT
6. Further information

1. WHAT LYSOBACT IS AND WHAT IT IS USED FOR

LYSOBACT contains two substances of natural origin-vitamin B6 (pyridoxine chloride) and lysozyme chloride. It belongs to a group of medicines that affect the respiratory system - local antiseptic. This medicine is used to treat mild sore throat, which is not accompanied by fever, small ulcers and sores in the mouth in adults and children older than 6 years.

2. BEFORE YOU TAKE LYSOBACT

Do not take LYSOBACT

- If you are allergic to Lysozyme, pyridoxine or other ingredients of this medicine
- If it is meant for a child under 6 years

Take special care with LYSOBACT

Taking of high doses of pyridoxine (vitamin B6) over a long period of time (several months, or even a year) may cause tingling, balance disorder, trembling of hands and feet, and reduced coordination of movements, which are usually reversible on discontinuation of the treatment.

This medicine should not be used for longer than 5 days, considering that the medicine could lead to an imbalance of the normal microflora of the oral cavity because of the risk of the spread of bacterial or fungal infection.

In the case of occurrence of other symptoms (fever, purulent sputum, difficulty swallowing), worsening of these symptoms or if they do not improve within 5 days, consult your doctor.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not use several antiseptics at the same time.

This medicine contains lysozyme hydrochloride and pyridoxine hydrochloride. There are other medicines with similar content.

Do not use them simultaneously with LYSOBACT so that you would not exceed the maximum recommended dose (see Dosage and method of administration).

Taking LYSOBACT with food and drink

Food and drink should not affect the efficiency of LYSOBACT compressed lozenges.

Pregnancy and breastfeeding

Before you start taking some medicine, consult your doctor or pharmacist.

Due to a lack of data, the use of LYSOBACT is not recommended during pregnancy and breastfeeding.

Driving and using machines

LYSOBACT should not affect your ability to drive and use machines.

Important information

LYSOBACT compressed lozenges contain milk sugar (lactose). So if you suffer from some form of sugar intolerance, tell your doctor before taking this medication.

3. HOW TO TAKE LYSOBACT

Always take LYSOBACT exactly according to the instructions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Dosage:

This medicine is intended for adults and children over 6 years.

The usual dose is 6 to 8 compressed lozenges during the day.

Method of application:

The medicine is administered orally (by mouth).

Compressed lozenge should be slowly melt under the tongue.

The frequency of application

Leave at least 1 hour between each dose.

Duration of treatment

The treatment lasts for 5 days. If your condition does not improve after five days of treatment, consult your doctor.

If you take more LYSOBACT than you should

If you take higher dose of the medicine than prescribed, immediately contact your doctor or pharmacist! after taking high doses of the medicine over a long period of time (several months, or even year) you may experience peripheral neuropathy (tingling, shaking of hands and feet, muscle weakness), which usually gets better after discontinuation of the treatment.

In case of overdose contact your doctor, so that he/she could provide assistance.

If you forget to take LYSOBACT

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. Never double-up on a dose to make up for the one you have missed.

If you stop taking LYSOBACT[®] compressed lozenges

Take this medicine as long as your doctor has prescribed. Abrupt discontinuation of the treatment should not adversely affect your body.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, LYSOBACT can cause side effects, although not everybody gets them.

It may cause allergic reactions such as:

- Skin rash, severe itching of the skin, skin sensitivity to sunlight (photosensitivity).
- Severe allergic reaction (anaphylactic shock), sudden swelling of the face and neck (Quincke's edema).

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LYSOBACT

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use LYSOBACT after the expiry date which is stated on the label, 5 years from the date of manufacture.

6. FURTHER INFORMATION**What LYSOBACT contains**

One LYSOBACT compressed lozenge contains: 20 mg of lysozyme hydrochloride and 10 mg of pyridoxine hydrochloride (Vitamin B6).

LYSOBACT compressed lozenge contains the following excipients: lactose, tragacanth, saccharin sodium, magnesium stearate, and vanillin.

What LYSOBACT looks like and contents of the pack

LYSOBACT compressed lozenges are white to off-white, with smooth undamaged edges, round shape, engraved division line on one side, flat smooth surface on the other side, with a diameter of 8 mm.

LYSOBACT compressed lozenges are packed in boxes which contain 10 compressed lozenges (1 blister with 10 lozenges) and in boxes which contain 30 compressed lozenges (3 blisters with 10 lozenges).

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufactuer

Bosnalijek d.d., Sarajevo, Jukićeva 53, Bosna i Hercegovina

Manufacturer of the medicinal product

Bosnalijek d.d., Sarajevo, Jukićeva 53, Bosna i Hercegovina

Date of last revision of the leaflet

March, 2014