

LYSOBACT Spray with anise flavor

LYSOBACT Spray with peppermint flavor

(20 + 1.5) mg / mL

Oromucosal spray, solution

LYSOZYME / CETYLPYRIDINIUM

• 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 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 active ingredients, lysozyme hydrochloride and cetylpyridinium chloride. It belongs to a group of medicines that act on the respiratory system - Preparations for the treatment of throat diseases.

LYSOBACT is used for:

- Local treatment of acute inflammatory diseases of the mucous membrane of the mouth and throat, such as gingivitis (gum disease), stomatitis (inflammation of the lining of the mouth) and ulcers (small lesions on the mucous membrane of the mouth).
- Additional local treatment of painful, irritated and sore throat and pharynx.
- As recommended by a doctor, before and after surgical procedures (on tonsils, larynx), as well as in injury or abscess, and after tooth extraction.

2. BEFORE YOU TAKE LYSOBACT

Do not use LYSOBACT

- If you are allergic to lysozyme hydrochloride, cetylpyridinium chloride, lidocaine hydrochloride and other anesthetics of the amide type or to any other ingredients.
- If you are allergic to egg white.
- If your child is younger than 6 years.

If any of these apply to you talk to your doctor or pharmacist before taking this medicine.

Take special care with LYSOBACT

Do not use this medicine for more than 5 days.

Diseases of the mucous membranes of the mouth and throat

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

The ulcers

If the lesions expand, extend their duration or in case of fever, talk to your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.

During the administration of LYSOBACT you should not simultaneously use other local antiseptics, to disinfect the mouth and / or throat.

Taking food and drink with LYSOBACT

The taking of food and drink should not affect the efficiency of medicine LYSOBACT Spray.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

As a precaution, do not use this medicine during pregnancy.

Breastfeeding

Do not use this medicine during breastfeeding.

Driving and using machines

It is not likely that LYSOBACT will affect your ability to drive and use machines.

3. HOW TO TAKE LYSOBACT

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

- Application of medicine is recommended for only one patient.
- Before the first application, it is necessary to remove the plastic cap from pump spray.

- Hold the bottle upright.
- Lift the nozzle of the spray away from the container until it is horizontal.
- If it is the first time you have used the spray, point the nozzle away from you and press down on the pump on the top of the container until you see a fine mist. The spray is now ready to use.
- Aim the spray at the sore area of your mouth or throat and press down on the pump to release one spray. Repeat this step to give the correct number of sprays.
- During spraying hold your breath. Do not swallow.
- When you have finished using the spray, push the nozzle of the spray back down against the container to store it safely.

Dosage

For individual dose, it is necessary to press the spray dispensing pump five times. The process can be repeated 3-6 times a day, with a minimum interval of 2 hours between dosages.

LYSOBACT is not recommended for children under 6 years.

If you use more LYSOBACT than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away.
If you use more medicine than you should, contact your doctor, so that he/she could provide medical help.

If you forget to use LYSOBACT

If you forget to use a dose, use it as soon as you remember. Do not apply a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

If you stop using LYSOBACT

Use this medicine as long as your doctor has prescribed.

If you suddenly stop using this medicine, do not expect any adverse effects on 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:

- Local hypersensitivity reactions.
- Severe allergic reaction (anaphylactic shock), sudden swelling of the face and neck (Quincke's edema).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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, 2 years from the date of manufacture.

6. FURTHER INFORMATION

What LYSOBACT contains

1 ml of medicine LYSOBACT contains lysozyme hydrochloride 20.00 mg (corresponding to 800 000 FIP U), cetylpyridinium chloride 1.50 mg.

In one pressure pump releases 0.20 ml of a solution containing 4 mg of lysozyme, and 0.3 mg of cetylpyridinium.

Medicine LYSOBACT Spray with anise flavor (20 + 1.5) mg / ml contains the following excipients: glycerol 85%, propylene glycol, saccharin sodium, methyl parahydroxybenzoate, anise flavor, propyl parahydroxybenzoate, sodium hydroxide, purified water.

Medicine LYSOBACT Spray with peppermint flavor (20 + 1.5) mg / ml contains the following excipients: glycerol 85%, propylene glycol, methyl parahydroxybenzoate, sodium saccharin, propyl parahydroxybenzoate, peppermint flavor, sodium hydroxide, purified water.

What LYSOBACT looks like and contents of the pack

Medicine LYSOBACT Spray with anise flavor (20 + 1.5) mg / ml is colorless to light yellow solution with anise scent.

Medicine LYSOBACT Spray with peppermint flavor (20 + 1.5) mg / ml is colorless to light yellow solution with peppermint scent.

Contents: 30 ml of solution in a vial made of brown glass with a pump spray and applicator for spray nebulizer.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Bosnalijek, doo, Jukićeva 53, Sarajevo, BiH