

## LYSOBACT COMPLETE SPRAY

(20 + 1.5 + 0.5) mg / mL Oromucosal spray, solution

LYSOZYME, CETYLPYRIDINIUM, LIDOCAINE

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*• 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.*

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*• 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 •*

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### What is in this leaflet?

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

#### *1. WHAT LYSOBACT COMPLETE SPRAY IS AND WHAT IT IS USED FOR*

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

#### **LYSOBACT COMPLETE SPRAY 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 COMPLETE SPRAY

### **Do not use LYSOBACT COMPLETE SPRAY**

- 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 COMPLETE SPRAY**

Use LYSOBACT COMPLETE SPRAY only when it is necessary to eliminate the pain and irritation.

LYSOBACT COMPLETE SPRAY is not intended for long-term, repeated and continuous administration.

Do not use this medicine for more than 5 days.

If there is no improvement within 5 days and / or in the case of other symptoms (severe sore throat, headaches, nausea, vomiting) or high temperature, consult your doctor.

If you have ever had an allergic reaction, avoid the use of LYSOBACT COMPLETE SPRAY.

If you or any of your relatives have porphyria (a rare disease of the blood pigment), LYSOBACT COMPLETE SPRAY should be used only in the case of vital and urgent conditions, with caution.

If you have difficulty swallowing, you should not use this medicine and you should consult your doctor.

When using it, you should be careful that the solution does not get into the eyes. If this accidentally happens, you need to wash your eyes with clean water or with eyewash solution, and you need to keep the eyelids open for at least 15 minutes.

### **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. Contact your doctor or pharmacist for advice if you are taking any of the following medicines:

- Beta blockers or other medicines for heart problems (eg, propranolol, mexiletine);
- Medicine for stomach ulcers (eg. Cimetidine);
- Diuretics, which help to remove excess fluid from your body;
- Medicine for epilepsy (eg, phenytoin or a barbiturate).

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

### **Taking food and drink with LYSOBACT COMPLETE SPRAY**

One hour after administration of LYSOBACT COMPLETE SPRAY do not consume any food and / or drink, as it may cause difficulty in swallowing and risk of aspiration (entry of food into the lungs) due to the presence of anesthetic in this medicine. Also, it is advisable to avoid the use of toothbrush and chewing gum, while the area of the mouth and / or throat is anaesthetized.

### **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 COMPLETE SPRAY will affect your ability to drive and use machines.

### ***Other warnings***

LYSOBACT COMPLETE SPRAY contains glycerol (85%), which can cause headache, gastric discomfort and diarrhea.

LYSOBACT COMPLETE SPRAY contains propylene glycol, an alcohol that can cause similar symptoms.

### ***3. HOW TO TAKE LYSOBACT COMPLETE SPRAY***

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.

In one pressure pump releases 0.20 ml of a solution containing 4 mg of lysozyme, 0.3 mg of cetylpyridinium and 0.1 mg of lidocaine hydrochloride.

LYSOBACT COMPLETE SPRAY is not recommended for children under 6 years.

LYSOBACT COMPLETE SPRAY contains no sugar and is suitable for use in diabetic patients.

### ***If you use more LYSOBACT COMPLETE SPRAY 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 someone accidentally swallows this spray, they need to contact a doctor or the nearest hospital with an emergency department. Take the medicine pack with you.

### ***If you forget to use LYSOBACT COMPLETE SPRAY***

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 COMPLETE SPRAY***

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 COMPLETE SPRAY can cause side effects, although not everybody gets them. Side effects are classified according to frequency: **very common**: 1 / 10; **common**: (1/10 - 1/100), **uncommon** (1/100 - 1/1000); **rare** (1 / 1,000 to 1 / 10,000); **very rare** (1 / 10,000), **Not known**: frequency cannot be determined from the available data.

Rarely there are allergic reactions such as anaphylactic shock, a sudden swelling of the face and neck (Quincke's edema), and local hypersensitivity reactions. In extremely rare cases, hypersensitivity reactions to lidocaine hydrochloride, after local injection, occurred in the form of localized swelling with mild difficulties in breathing, or as generalized rash.

Gastrointestinal disorders occur rarely and are mostly associated with the application of higher doses than recommended.

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 COMPLETE SPRAY

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use LYSOBACT COMPLETE SPRAY after the expiry date which is stated on the label, 2 years from the date of manufacture.

#### 6. FURTHER INFORMATION

##### **What LYSOBACT COMPLETE SPRAY contains**

1 ml of medicine LYSOBACT COMPLETE SPRAY contains lysozyme hydrochloride 20.00 mg (corresponding to 800 000 FIP U), cetylpyridinium chloride 1.50 mg and 0.50 mg of lidocaine hydrochloride.

In one pressure pump releases 0.20 ml of a solution containing 4 mg of lysozyme, 0.3 mg of cetylpyridinium and 0.1 mg of lidocaine.

Medicine LYSOBACT COMPLETE SPRAY contains the following excipients: glycerol 85%, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, peppermint flavor, sodium hydroxide, purified water.

##### **What LYSOBACT COMPLETE SPRAY looks like and contents of the pack**

Medicine LYSOBACT COMPLETE SPRAY 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

