

**Lysozyme Hydrochloride +
Cetylpyridinium Chloride +
Lidocaine Hydrochloride**

LYSOBACT COMPLETE SPRAY®
20 mg/1.5 mg/0.5 per mL
Oromucosal Spray Solution (Peppermint)
Anti-inflammatory/Antiseptic/Local Anesthetic

Read carefully this leaflet as it contains information that is important to you!

This product is available without medical prescription. You should observe the recommendations contained in this leaflet in order to get the best results from the use of this product.

Keep this leaflet. You may need to read it again.

If you have any further questions, consult your doctor or pharmacist.

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1. What LYSOBACT COMPLETE SPRAY® is and what it is used for
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1. What LYSOBACT COMPLETE SPRAY® is and what it is used for

LYSOBACT COMPLETE SPRAY® contains three active ingredients: lysozyme hydrochloride, cetylpyridine chloride and lidocaine hydrochloride.

It belongs to a group of medicines acting on the respiratory system – preparations for treating throat disorders.

LYSOBACT COMPLETE SPRAY® is used for:

- Local treatment of acute inflammatory diseases of oral cavity and pharynx mucosa, such as gingivitis (gum disease), stomatitis (oral cavity mucosa inflammation) and aphthae (small ulcers on the oral mucosa).
- Adjuvant local treatment of painful, irritable and inflamed throat and pharynx.
- At doctor's recommendation, before and after surgeries (tonsils, larynx), and in case of injuries or abscess, as well as after a tooth extraction.

2. Before you start using LYSOBACT COMPLETE SPRAY®

Tell your doctor if you take any other medicines, suffer from a chronic illness, a metabolism disorder, if you are hypersensitive to medicines or have ever had allergic reactions to some of them.

Do not use LYSOBACT COMPLETE SPRAY®:

- If you are hypersensitive to lysozyme hydrochloride, cetylpyridine chloride, lidocaine hydrochloride as well as other amide-type anaesthetics or any other drug ingredient.
- If you are hypersensitive to egg white.
- If your child is below 6 years of age.

If any of the above-mentioned refers to you, consult your doctor or pharmacist before using this medicine.

Take special care with LYSOBACT COMPLETE SPRAY®

Use LYSOBACT COMPLETE SPRAY® only when it is necessary, in order to eliminate pain and irritability.

LYSOBACT COMPLETE SPRAY® is not intended for long-lasting, repeated and continuous usage.

In case no improvement occurs within 5 days and/or if other symptoms appear (high body temperature, expectoration of pus, difficulty swallowing), consult your doctor.

If you have ever had allergic reactions, avoid usage of LYSOBACT COMPLETE SPRAY®.

During usage of LYSOBACT COMPLETE SPRAY, severe acute hypersensitivity reactions can occur, such as urticaria, gradual swelling of the face and tongue (angioedema) also involving airways, narrowing of the airways, circulatory complications and anaphylactic shock.

Additionally, isolated cases of severe reactions on the skin and mucosa have been reported. Some of these severe reactions can be life-threatening. In case symptoms which indicate a hypersensitivity reaction occur, it is necessary to discontinue this medicine.

If you or some of your relatives had porphyria (rare blood pigment disorder), use LYSOBACT COMPLETE SPRAY® only in case of vital and urgent conditions, exercising special precaution.

If you have difficulties with swallowing, you must not use this medicine and you need to consult your doctor.

When using this medicine, ensure that this solution does not enter your eyes. If that accidentally happens, rinse your eyes with clean water or with the eyewash, and keep the eyelids open for at least 15 minutes.

Using other medicines with LYSOBACT COMPLETE SPRAY®

Keep in mind that this information may refer to the medicines you are no longer taking as well as those you plan to take in future. Tell your doctor if you are taking, or have recently taken another medicine, including the medicine available without medical prescription.

Consult your doctor or pharmacist if you take any of the following:

- Beta-blockers or other medicines for heart problems (e.g. propranolol, mexiletine);
- Medicine for treating stomach ulcer (e.g. cimetidine);
- Diuretics, which help in eliminating the excess fluids from your organism through urinating;
- Medicine for epilepsy (e.g. phenytoin or another barbiturate).

While using LYSOBACT COMPLETE SPRAY®, you must not simultaneously take other local antiseptics, for the purpose of disinfecting mouth and/or throat.

Using food and drinks with LYSOBACT COMPLETE SPRAY®

Do not take any food or drinks one hour after using LYSOBACT COMPLETE SPRAY®, because difficult swallowing may appear as well as danger from aspiration (entering of food into lungs) due to presence of anaesthetic in this medicine. Additionally, it is advised to avoid teeth brushing and chewing gum while the mouth and/or throat is being anaesthetized.

Pregnancy and lactation

Inform your doctor or pharmacist about your pregnancy prior to taking any medicine.

Pregnancy

As a precaution, it is not recommended to use this medicine in pregnancy.

Lactation

It is not recommended to use this medicine in the period of breast-feeding.

Driving and using machines

No significant effects on these abilities of a patient are known.

Other warnings

LYSOBACT COMPLETE SPRAY® contains glycerol (85%), which may cause headache, stomach difficulties and diarrhoea.

LYSOBACT COMPLETE SPRAY® contains propylene glycol, which may induce symptoms similar to alcohol.

LYSOBACT COMPLETE SPRAY contains methyl parahydroxybenzoate and propyl parahydroxybenzoate that may cause allergic reactions.

3. How to use LYSOBACT COMPLETE SPRAY®

Use this medicine according to the given directions.

If you think that this medicine has a too strong or too weak effect, consult your doctor or pharmacist.

Method of usage

- It is recommended to use this medicine for one patient only.
- Prior to first usage, it is necessary to remove the plastic closure from the spraying pump.

- After that, place the applicator onto the spray pump using a mild pressure.
- The applicator can be moved sideways and ensures proper application of the spray into the oral cavity.
- Turn the applicator upwards, under the right angle in relation to the bottle.
- Before the first application of the spray, press the spray pump several times in order to accomplish an equal spraying.
- Open your mouth completely, direct the applicator towards the diseased site and press the spray pump as many times as it is directed in drug dosage.
- Hold your breath during the spraying. Do not swallow.
- After applying the medicine, turn the applicator downwards, which will block the further spraying.

Dosage

For a single dose, it is necessary to press the spray pump five times. The procedure can be repeated 3-6 times a day, with minimal intervals of 2 h between the dosing.

When you press the spray pump once, 0.20 ml of the solution is released, which contains 4 mg lysozyme, 0.3 mg cetylpyridine and 0.1 mg lidocaine hydrochloride.

LYSOBACT COMPLETE SPRAY® is not recommended to children aged below 6 years.

LYSOBACT COMPLETE SPRAY® does not contain sugar and it is suitable for usage in diabetics.

Duration of treatment

Duration of the treatment is restricted to 5 days.

If you apply more LYSOBACT COMPLETE SPRAY® than you should

If you applied more spray than you should, immediately contact your doctor or pharmacist!

If you apply more LYSOBACT COMPLETE SPRAY® than you should or accidentally swallow certain amount of the liquid directly from the bottle, contact your doctor immediately. Bring the drug pack with you, so that the healthcare personnel could identify which medicine you have swallowed.

If you forget to apply LYSOBACT COMPLETE SPRAY®

If you forget to use the medicine, do not use the double dose afterwards, but continue the usage according to the usual schedule.

If you forget to apply LYSOBACT COMPLETE SPRAY®, use it as soon as possible. After that, continue with drug usage at the usual schedule and in the recommended way.

If you stop using LYSOBACT COMPLETE SPRAY®

Use this medicine as long as your doctor has prescribed you.

If you suddenly stop using this medicine, no harmful effects on your organism are expected.

If you are not certain or have questions related to usage of LYSOBACT COMPLETE SPRAY® consult your doctor or pharmacist.

4. Possible side effects

Like other medicines, LYSOBACT COMPLETE SPRAY® can cause side effects.

Very common	Appear in more than 1 in 10 treated patients
Common	Appear in 1 to 10 in 100 treated patients
Uncommon	Appear in 1 to 10 in 1000 treated patients
Rare	Appear in 1 to 10 in 10 000 treated patients
Very rare	Appear in less than 1 in 10 000 treated patients
Frequency unknown	Frequency cannot be estimated from the available data

Allergic reactions such as anaphylactic shock, sudden swelling of the face and neck (Qwincke's oedema), as well as local hypersensitivity reactions appear rarely. In extremely rare cases, hypersensitivity reactions to lidocaine hydrochloride, following local injection, appear in the form of a localised oedema with mild breathing difficulties, or as a generalised rash.

Side effects of unknown frequency: allergic reactions including allergic oedema, skin rash, urticaria, narrowing of airways, and circulatory complications.

Isolated cases of severe skin reactions (erythema multiforme and Stevens-Johnson syndrome) have been reported.

Gastrointestinal system disorders appear rarely in the form of oral mucosal irritations and they are mainly associated with usage of doses which are higher than recommended.

FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov

Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

5. How to store LYSOBACT COMPLETE SPRAY®

Keep LYSOBACT COMPLETE SPRAY® out of the reach and sight of children.

Store at temperatures not exceeding 30°C. Do not freeze. Shelf life: 36 months.

LYSOBACT COMPLETE SPRAY® must not be used after the expiry date given on the pack.

6. Further information

What LYSOBACT COMPLETE SPRAY® contains

Each ml of LYSOBACT COMPLETE SPRAY® contains
 Lysozyme Hydrochloride 20.00 mg (corresponding to 800 000 FIP U)
 Cetylpyridine Chloride 1.50 mg
 Lidocaine Hydrochloride 0.50 mg.

When pressing the spray pump once, it will release 0.20 ml of the solution which contains 4 mg of lysozyme, 0.3 mg cetylpyridine and 0.1 mg lidocaine.

LYSOBACT COMPLETE SPRAY® contains the following excipients: Glycerol 85%, Propylene Glycol, Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Peppermint Flavour, Sodium Hydroxide, Purified Water.

What LYSOBACT COMPLETE SPRAY® looks like and contents of the pack

LYSOBACT COMPLETE SPRAY® is colourless to slightly yellow solution with peppermint odour.

Contents of the pack: 30 ml of the solution in amber glass bottle with a spray pump and applicator for the spray.

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Proposed issuing regime

Available without medical prescription.

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