

**Lysozyme Hydrochloride +
Pyridoxine Hydrochloride
(Vitamin B6)**

**LYSOBACT P SPRAY®
20 mg/10 mg per mL
Oromucosal Spray Solution (Banana Flavor)
Anti-inflammatory/Vitamin**

Read carefully this leaflet before use as it contains information which is important to you!

This medicine is available without a medical prescription. You should observe this leaflet in order to get the best results by the use of the medicine. Keep the leaflet. You may need to read it again. If you have further questions, consult your doctor or pharmacist.

What is in this leaflet

1. What LYSOBACT P SPRAY is and what it is used for
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1. What LYSOBACT P SPRAY is and what it is used for

LYSOBACT P SPRAY contains two active ingredients named lysozyme hydrochloride and pyridoxine hydrochloride. It belongs to a group of medicines acting on the respiratory system – local antiseptic agent.

This medicine is used for the treatment of mild sore throat without fever, mouth ulcers and small mouth sores in adults and children over 2 years of age.

2. Before you start using LYSOBACT P SPRAY

Do not use LYSOBACT P SPRAY

- If you or your child are hypersensitive to lysozyme hydrochloride or pyridoxine hydrochloride or any other ingredients (listed in section 6. Further information).
- If you or your child are allergic to eggs (because lysozyme is extracted from chicken egg albumen).
- If your child is below 2 years of age.

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

Take special care with LYSOBACT P SPRAY

When using high pyridoxine doses (B6 vitamin) for a longer time period (several months, or even years) pins and needles, balance disorder, hand and foot tremor, as well as difficult coordination of movements may appear, which usually vanish after discontinuing the medicine.

You must not take this medicine for longer than 5 days, as it can lead to imbalance in mouth microflora with the risk of spreading the bacterial or fungal infection.

Sore throat

If other symptoms appear (high temperature, purulent sputum, difficult swallowing), aggravation of these symptoms or if there is no improvement after 5 days, **consult your doctor.**

Mouth aphthae and sores

If the lesions are spread, their duration prolonged or if high temperature occurs, **contact your doctor immediately.**

Using other medicines with LYSOBACT P 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. Inform your doctor if you are taking, or have recently taken another medicine, including the one available without medical prescription.

Do not concomitantly use several medicines containing an antiseptic agent.

This medicine contains lysozyme hydrochloride and pyridoxine hydrochloride. Other medicines contain it too. Do not use them concomitantly in order not to exceed the maximum recommended doses (see dosage and method of administration).

Using food and drinks with LYSOBACT P SPRAY

Presence of food and drinks should not affect the effectiveness of LYSOBACT P SPRAY.

Pregnancy and lactation

Consult your doctor or pharmacist before you start taking any medicine.

Pregnancy

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

Lactation

As there is insufficient data on lysozyme's excretion into the breast milk, as well as high proportion of pyridoxine, usage of this medicine should be avoided during the lactation period.

Driving and using machines

LYSOBACT P SPRAY does not affect the patient's ability to drive and use machines.

Other warnings

LYSOBACT P SPRAY contains sorbitol non-crystallising (E420). If your doctor told you that you have intolerance to some sugars, consult your doctor before you take this medicine. It might have mild laxative effect.

LYSOBACT P SPRAY contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (delayed hypersensitivity reactions are also possible).

LYSOBACT P SPRAY contains propylene glycol, which may cause alcohol-like symptoms.

3. HOW TO USE LYSOBACT P SPRAY

Take the medicine according to the enclosed leaflet. If you think that the medicine's action is too weak or too strong, consult your doctor or pharmacist.

Method of administration

- It is recommended to use the drug for one patient only.
- Before the first application, it is necessary to remove the protective cap from the spray pump.
- After that, place the spray pump applicator on the spray pump by a light press.
- Applicator can be moved sideways and it ensures proper application of spray into the mouth cavity.
- Applicator should be turned upwards at a right angle from the bottle.

- Before the first application of the spray, press the spray pump several times until reaching an equal spray.
- The mouth should be completely opened, the applicator needs to be directed towards the affected area and press the spray pump as many times as noted in the posology.
- Hold the breath during the spraying.
- After the application of the spray, the applicator should be turned downwards, where the spraying is blocked.

Dosage

This medicine is intended for use in adults and children over 2 years of age.
Pumps delivers per single actuation 0.20 ml of the solution containing 4 mg of lysozyme and 2 mg of pyridoxine.
For a single dose, it is necessary to press the spray pump five times.

Adults and children over 6 years of age: press the spray pump five times, 6-8 times a day.
Children aged 2-6: press the spray pump five times, 3 times a day.
Children below 2 years of age: LYSOBACT P SPRAY is not recommended for use in children below 2 years of age.

An interval of at least 1 hour has to pass between each application.

The treatment lasts for 5 days. If there is no improvement after 5 days it is necessary to consult a doctor.

If you apply more LYSOBACT P SPRAY than you should
If you take more LYSOBACT P SPRAY than you should, contact your doctor or pharmacist straight away!

If you or your child apply more LYSOBACT P SPRAY than you should or accidentally swallow certain amount of the liquid directly from the bottle, contact your doctor straight away. Bring the medicine pack with you, so that the healthcare personnel could identify which medicine you have swallowed.
When using high drug doses for a longer time period (several months, or even years), peripheral neuropathy may appear (pins and needles, hand and feet tremor, muscular weakness) that usually disappears upon discontinuation of the medication.

If you forget to apply LYSOBACT P SPRAY
If you forgot to take the medicine, do not take double dose of the medicine afterwards, but continue drug administration according to the usual schedule.

If you forget to take LYSOBACT P SPRAY, take it as soon as you remember. After that, continue taking LYSOBACT P SPRAY at your regular schedule and in the recommended manner.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4.Possible side effects

Like other medicines, LYSOBACT P SPRAY can cause side effects, although not everybody gets them.

The following allergic reactions may appear:

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

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

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

5.How to store LYSOBACT P SPRAY

Store at temperatures not exceeding 30°C.
Shelf life: 36 months.
Do not use this medicine after the expiry date which is stated on the label.

6.Further information

What LYSOBACT P SPRAY contains
1 ml of LYSOBACT P SPRAY contains lysozyme hydrochloride 20.00 mg (corresponding to 800 000 FIP U) and pyridoxine hydrochloride 10.00 mg.
Pumps delivers per single actuation 0.20 ml of the solution containing 4 mg of lysozyme and 2 mg of pyridoxine.

LYSOBACT P SPRAY contains the following excipients: cetylpyridium chloride, sorbitol liquid non-crystallising (E420), propylene glycol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), banana water, saccharin sodium, sodium hydroxide, purified water.

What LYSOBACT P SPRAY looks like and contents of the pack
LYSOBACT P SPRAY is a clear, colourless to yellow solution.
Contents of the pack: amber glass bottle 30 ml with a spray pump with protective cap and applicator for the spray.
Pumps delivers per single actuation 0.20 ml.

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