

Package leaflet: Information for the user

Lysopadol® **17.86 mg/ml Oromucosal spray, solution** ambroxol hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Lysopadol Spray is and what it is used for
2. What you need to know before you take Lysopadol Spray
3. How to take Lysopadol Spray
4. Possible side effects
5. How to store Lysopadol Spray
6. Contents of the pack and other information

1. What Lysopadol Spray is and what it is used for

- Lysopadol Spray contains the active substance Ambroxol hydrochloride. The active substance is the part of the spray that gives the therapeutic effect you need.
- Lysopadol Spray has a local anaesthetic effect which relieves the pain in acute sore throat.
- Lysopadol Spray is used to relieve the pain in acute sore throat for adults and children over 12 years of age.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Lysopadol Spray

Do not take Lysopadol Spray

- If you are allergic to ambroxol hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lysopadol Spray.

- You should not use Lysopadol Spray for more than 3 days. If you still have symptoms after 3 days or if you have a high fever, please consult a doctor.
- If you have liver or kidney problems, ask your doctor before using Lysopadol Spray.
- Lysopadol Spray is not suitable for the treatment of painful lesions in the mouth (e.g. ulcers or sores).
- If you have mouth ulcers, please consult a doctor.
- Shortness of breath (dyspnoea) may be observed due to an underlying condition (e.g. swollen throat). Another reason could be a feeling of tightness in the throat due to the local anaesthetic effect of Lysopadol Spray. A further cause could be an allergic reaction which may also cause your mouth and throat to swell.
- Your throat and mouth may feel less sensitive than usual (numb).
- There have been reports of severe skin reactions associated with the administration of ambroxol hydrochloride. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using Lysopadol Spray and contact your doctor immediately.

Children

Do not give this medicine to children under 12 years of age.

Other medicines and Lysopadol Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Ambroxol passes into the body of the unborn child. You should not take Lysopadol Spray if you are pregnant, especially not during the first three months.
- Ambroxol passes into breast milk. If you are breastfeeding you should not take Lysopadol Spray.

Driving and using machines

Lysopadol Spray is not known to affect your ability to drive or use machines.

Lysopadol Spray contains ethanol and propylene glycol

- This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose (4 sprays).
- This product contains propylene glycol which may cause mucosal irritation.

3. How to take Lysopadol spray

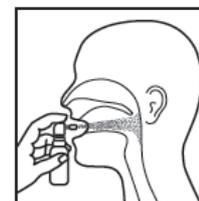
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

For adults and children over 12 years of age, apply one dose (4 sprays) into the back of the throat when you need pain relief. You should not take the spray more than 6 times per day.

Follow the instructions before each use:

1. Remove protective cap.
2. Before using for the first time, activate the pump 5 times so that an even spray mist is released.
If you have not used the spray for a long time, activate the pump once before you apply the spray again.
3. For application use the spray bottle in an upright position with the nozzle targeted at the back of the throat. Then push down the pump head completely and apply 4 sprays.
4. Replace protective cap after use.



Clinical data have shown a rapid onset of action (with the first effect being observed after 15 minutes). The effect will last for at least 3 hours. You should not use Lysopadol Spray for more than 3 days. If you still have symptoms after 3 days or if you have a high fever, please consult a doctor.

If you take more Lysopadol Spray than you should

If you take more than 4 sprays per application or if you use the spray more than 6 times per day ask advice from your doctor or pharmacist if you observe any untoward symptoms.

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

4. Possible side effects

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

If one of following side effects occurs, stop taking Lysopadol Spray and contact your doctor immediately:

- allergic reaction with localized swelling of the face, lips, mouth, tongue and / or throat (angioedema). This may cause a feeling of tightness in the throat, difficulty in swallowing or breathing.
- rapidly occurring allergic reactions affecting the whole body (anaphylactic reactions including anaphylactic shock).

The severity of allergic reactions may increase if you take the product again, or if you take another product containing the same ingredients.

Other side effects that may occur:

Common: may affect up to 1 in 10 people

- feeling sick (nausea)
- numbness of mouth, tongue and throat (oral and pharyngeal hypoaesthesia)
- taste disturbance (dysgeusia)

Uncommon: may affect up to 1 in 100 people

- indigestion (dyspepsia)
- tummy pain (upper abdominal pain)
- dry mouth

Rare: may affect up to 1 in 1,000 people

- hypersensitivity reactions
- rash, urticaria
- diarrhoea
- dry throat

Not known: frequency cannot be estimated from the available data

- anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues) and pruritus
- severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis)
- vomiting

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

Reporting of 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. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie;

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lysopadol Spray

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle label. The expiry date (EXP) refers to the last day of that month.
- Do not store above 30°C.
- After first opening it can be used for 6 months.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lysopadol spray contains

- The active substance is ambroxol hydrochloride.
- One actuation contains 2.5 mg ambroxol hydrochloride.
- One ml of the spray contains 17.86 mg of ambroxol hydrochloride.

The other ingredients are:

- citric acid monohydrate
- disodium phosphate dihydrate
- polysorbate 20
- sucralose
- cooling flavour (contains propylene glycol)
- eucalyptus-menthol flavour (contains propylene glycol)
- ethanol
- purified water

What Lysopadol spray looks like and contents of the pack

- This medicinal product is presented as a clear and almost colourless solution.
- The spray is available in a glass bottle with dose pump and throat adapter.
- Marketed pack size 20 ml.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder for Lysopadol Spray is:

sanofi-aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: +353 1 4035600
Fax: +353 1 4035687
email: IEmedinfo@sanofi.com.

The manufacturer of Lysopadol Spray is:

Pharbil Waltrop GmbH
Im Wirrigen 25
45731 Waltrop
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

- Austria: Mucoangin 17,86 mg/ml Spray zur Anwendung in der Mundhöhle
- Belgium/Luxembourg: Mucoangin 2,5 mg/pulvérisation, Solution pour pulvérisation buccale
- Cyprus, Greece: Lysospray
- Denmark: Mucoangin
- France: LYSOPAÏNE MAUX DE GORGE AMBROXOL MENTHE 17,86 mg/ml SANS SUCRE, solution pour pulvérisation buccale édulcorée au sucralose
- Ireland: Lysopadol 17.86 mg/ml Oromucosal Spray, Solution
- Italy: Zerinol Gola 2,5 mg/erogazione spray per mucosa orale, soluzione
- Netherlands: Mucoangin Spray 2,5 mg, spray voor oromucosaal gebruik
- Spain: LIZIPAINA® ambroxol 17,86 mg/ml solución para pulverización bucal
- Sweden: Mucoangin 2,5 mg/sprayning, munhålespray, lösning

This leaflet was last revised in November 2019