

Package leaflet: Information for the user

Lysopadol® Mint **20 mg Lozenges** 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 has 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 Mint is and what it is used for
2. What you need to know before you take Lysopadol Mint
3. How to take Lysopadol Mint
4. Possible side effects
5. How to store Lysopadol Mint
6. Contents of the pack and other information

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

Lysopadol Mint contains the active substance ambroxol hydrochloride. The active substance is the part of the lozenges that gives the therapeutic effect you need.

Lysopadol Mint has a local anaesthetic effect which relieves the pain in acute sore throat. Within 20 minutes, the main clinical study showed a positive onset of action in 73% of the patients. The duration of effect will last for at least 3 hours.

Lysopadol Mint is used to:

- relieve the pain in mild to moderate symptoms of acute sore throat

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

Do not take Lysopadol Mint

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

Talk to your doctor or pharmacist before taking Lysopadol Mint.

- You should not use Lysopadol Mint 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 been told by your doctor that you have an intolerance to some types of sugar, contact your doctor before taking this medicinal product. See also "Important information about some of the ingredients of Lysopadol Mint".
- If you have liver or kidney problems, ask your doctor before using Lysopadol Mint.
- Lysopadol Mint 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 disease (e.g. swollen throat). Another reason could be a feeling of tightness in the throat due to the local anaesthetic effect of Lysopadol Mint. 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 Mint and contact your doctor immediately.

Children

If you are under 12 years of age you should not use Lysopadol Mint.

Other medicines and Lysopadol Mint

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 breast-feeding, 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 Mint if you are pregnant, especially not during the first three months.

Ambroxol passes into breast milk. If you are breast-feeding you should not take Lysopadol Mint.

Driving and using machines

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

Lysopadol Mint contains sorbitol, lactose and sodium

One lozenge contains 1.37 g sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

One lozenge contains less than 1 mg lactose monohydrate (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Lysopadol Mint is essentially sugar free.

This medicine contains less than 1 mmol sodium (23 mg) per lozenge that is to say essentially 'sodium-free'.

3. How to take Lysopadol Mint

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, 1 lozenge should be sucked when you need pain relief. You should not take more than 6 lozenges per day.

You should not use Lysopadol Mint 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 Mint than you should

No specific overdose symptoms have been reported. If you take too many lozenges (more than 6 per day)

ask advice from your doctor or pharmacist if you observe any symptoms.

If you have any further questions on the use of this product, 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 occur, stop taking Lysopadol Mint and contact your doctor immediately:

- allergic reaction with localized swelling in 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)

Further 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 hypoesthesia)
- taste disturbance (dysgeusia)

Uncommon: may affect up to 1 in 100 people

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

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

- hypersensitivity reactions
- rash, urticaria
- dry throat

Not known: frequency cannot be estimated from the available data

(a precise frequency estimation is not possible, as the side effects did not occur in a set of clinical trial of 1226 patients. The frequency category is probably not greater than uncommon, but might be lower)

- 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 Mint

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 blister foil. The expiry date (EXP) refers to the last day of that month.

Do not store Lysopadol Mint above 30°C.

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 Mint contains

The active substance is ambroxol hydrochloride. One lozenge contains 20 mg ambroxol hydrochloride.

The other ingredients are

- peppermint aroma (containing gum arabic, Chinese peppermint oil, maltodextrin and lactose monohydrate)
- sorbitol
- saccharin sodium
- macrogol 6000
- talc

What Lysopadol Mint 20 mg Lozenges look like and contents of the pack

Lysopadol Mint 20 mg Lozenges are round, white tablets with bevelled edges. Both sides are flat. Lysopadol Mint 20 mg Lozenges are available in plastic/aluminium blister packs.

Pack sizes:

8, 10, 16, 18, 20, 24, 27, 30, 32, 36, 40, 45, 48 and 50 lozenges.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder for Lysopadol Mint

is:

sanofi-aventis Ireland Ltd. T/A SANOFI

Citywest Business Campus

Dublin 24

Ireland

Tel: +353 1 4035600

Fax: +353 1 4035687

e-mail: IMedinfo@sanofi.com.

The manufacturer of Lysopadol Mint is:

Delpharm Reims S.A.S.
10 rue Colonel Charbonneaux
51100 Reims
France

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

Belgium: Lysopadol Mint®
Denmark, Netherlands, Sweden: Mucoangin® Mint

This leaflet was last revised in March 2020