

Package leaflet: Information for the user

Prosperan® Cough Lozenges

Active substance: dried ivy leaf extract

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. In order to achieve the best possible treatment outcome, however, Prosperan® Cough Lozenges must be used in line with the instructions.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your symptoms worsen or do not improve after 7 days, you must in any case see a doctor.
- If any of the listed side effects significantly impairs you or you notice side effects not listed in this package leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. What Prosperan® Cough Lozenges are and what they are used for
2. What you need to know before you take Prosperan® Cough Lozenges
3. How to take Prosperan® Cough Lozenges
4. Possible side effects
5. How to store Prosperan® Cough Lozenges
6. Other information

1. What Prosperan® Cough Lozenges are and what they are used for

Prosperan® Cough Lozenges are a herbal medicine for catarrhal disorders affecting the airways.

Prosperan® Cough Lozenges are used to alleviate the symptoms of chronic-inflammatory bronchial disorders; catarrhal disorders affecting the airways.

2. What you need to know before you take Prosperan® Cough Lozenges

Do not take Prosperan® Cough Lozenges

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of this medicine.

Special care with taking Prosperan® Cough Lozenges is required

If your symptoms persist, or if you experience trouble breathing, fever or purulent or bloody discharge, you should immediately consult a doctor.

Children:

Prosperan® Cough Lozenges are not intended to be taken by children under 6 years of age.

Other medicines and Prosperan® Cough Lozenges
No studies have been performed. So far, no interactions have become known.

Tell your doctor or pharmacist if you are taking/using or

have recently taken/used any other medicines, including over-the-counter medicines.

Pregnancy and breast-feeding

This medicine should not be used during pregnancy and while breast-feeding since no sufficient studies are available.

Driving and using machines:

No special precautions are necessary.

Important information about specific other ingredients of Prosperan® Cough Lozenges:

This medicine contains sorbitol and maltitol. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

3. How to take Prosperan® Cough Lozenges

Always use Prosperan® Cough Lozenges exactly as instructed in this leaflet. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by a doctor, the usual dose is: Adults and children from 12 years of age suck 1 lozenge (equivalent to 104mg dried ivy leaf extract or 624mg drug per day) 4 times daily.

Children between 6 and 12 years of age suck 1 lozenge (equivalent to 52 mg dried ivy leaf extract or 312mg drug per day) twice daily.

Method of administration

To be taken orally and sucked.

Let the lozenges dissolve in your mouth after meals (do not lie down while doing so).

Duration of use

Treatment duration depends on the type and severity of the illness; it should usually be 1 week. Should the symptoms, however, persist for longer than 1 week, medical advice should be sought.

Please talk to your doctor or pharmacist if you feel that the effect of Prosperan® Cough Lozenges is too strong or too weak.

If you take more Prosperan® Cough Lozenges than you should:

You should not take more Prosperan® Cough Lozenges per day than stated in the dosing instructions or prescribed by the doctor. Taking significantly larger amounts (more than three times the daily dose) can cause nausea, vomiting and diarrhoea. In this case, you should see your doctor.

If you forget to take Prosperan® Cough Lozenges:

Do not take the double dose the following time, but continue intake as prescribed by the doctor or described in the package leaflet.

4. Possible side effects

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

The classification of side effects is based on the following frequencies:

Very common: more than 1 in 10 treated persons

Common: 1 to 10 in 100 treated persons

Uncommon: 1 to 10 in 1,000 treated persons

Rare:	1 to 10 in 10,000 treated persons
Very rare:	less than 1 in 10,000 treated persons
Not known:	The frequency cannot be estimated from the available data

Possible side effects:

After taking medicines containing ivy, allergic reactions such as trouble breathing, swelling, reddening of skin and mucosa and itching may occur rarely.

In sensitive people, gastrointestinal symptoms such as nausea, vomiting, diarrhoea may occur uncommonly. You must stop taking Prospan® Cough Lozenges upon experiencing the first signs of a hypersensitivity reaction. If any of the listed side effects significantly impairs you or you notice side effects not listed in this package leaflet, please inform your doctor or pharmacist.

5. How to store Prospan® Cough Lozenges

Keep out of the reach and sight of children!

Do not store above 25°C.

Store in the original pack in order to protect the content from moisture.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

6. Other information

What Prospan® Cough Lozenges contain

The active substance is: dried ivy leaf extract 1 lozenge contains 26 mg dried ivy leaf extract (5 – 7.5 : 1). Extracting agent: Ethanol 30% (m/m).

The other ingredients are:

maltitol solution, sorbitol solution 70% (non-crystallising) (Ph.Eur.), gum arabic, citric acid, acesulfame K, medium-chain triglycerides, orange flavouring, menthol flavouring, purified water.

1 lozenge contains 0.53 g maltitol and 0.53 g sorbitol, equivalent to approx. 0.09 bread units.

1 lozenge contains 2.6 kcal = 10.6 kJ.

What Prospan® Cough Lozenges look like and contents of the pack

Prospan® Cough Lozenges are available in original packs of 20 (N 1) lozenges.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in October 2018.

Notes:

Prospan® Cough Lozenges contain a herbal active substance. Due to this herbal extract, the colour and taste of Prospan® Cough Lozenges may vary slightly. Both these factors do, however, not affect the quality of the product.

