

# PROSPAN®

## Cough Lozenges

### Package leaflet: Information for the user

### Prospan® Cough Lozenges

Active ingredient: Ivy leaf dry extract

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

**This medicine is available without prescription. However, you still need to use Prospan® Cough Lozenges as described in this leaflet to get the best possible results from them.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if your symptoms get worse or do not improve after 7 days.
- If any of the listed side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### What is in this leaflet:

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

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

**Prospan® Cough Lozenges are a herbal medicine for diseases of the respiratory tract involving catarrh.**

Prospan® Cough Lozenges are used to alleviate the symptoms of chronic inflammatory bronchial diseases, as well as coughs and colds affecting the respiratory tract.

For use in adults, adolescents and children aged 6 years and above.

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

##### Do not use Prospan® Cough Lozenges:

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Prospan® Cough Lozenges. Please consult a doctor in the event of fever, shortness of breath, or purulent or bloody sputum, or in the event of symptoms that last for longer than one week or that are non-specific.

##### Children:

Prospan® Cough Lozenges are not suitable for use in children under 6 years of age.

##### Other medicines and Prospan® Cough Lozenges:

No studies have been conducted. No interactions are known to date.

Tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines. This includes medicines obtained without a prescription.

##### Pregnancy and breast-feeding:

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. This medicine should not be used during pregnancy and breast feeding as no adequate studies are available.

##### Driving and using machines:

No specific precautions are required.

##### Important information about some of the ingredients of Prospan® Cough Lozenges:

This medicine contains sorbitol and maltitol. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking Prospan® Cough Lozenges.

#### 3. How to take Prospan® Cough Lozenges

Always take Prospan® Cough Lozenges exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dosage is: Adults and children aged 12 years and above: dissolve 1 lozenge in the mouth 4 times per day (equivalent to 104 mg ivy leaf dry extract or 624 mg drug per day).

Children aged 6-12 years: dissolve 1 lozenge in the mouth 2 times per day (equivalent to 52 mg ivy leaf dry extract or 312 mg drug per day).

No adequate data are available to make concrete dose recommendations in case of impaired liver and/or kidney function.

##### Method of administration

For oral use (to be dissolved in the mouth).

The lozenges are to be allowed to dissolve in the mouth after food (not while lying down).

##### Duration of use

The duration of treatment depends on the type and severity of the symptoms and is generally one week. If symptoms persist for longer than 1 week, please seek medical advice.

If you have the impression that the effect of Prospan® Cough Lozenges is too strong or too weak, talk to your doctor or pharmacist.

##### If you take more Prospan® Cough Lozenges than you should:

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

##### If you forget to take Prospan® Cough Lozenges:

Do not take a double dose to make up for a forgotten dose; instead, continue taking the medicine as prescribed by your doctor or as described in the package leaflet.

#### 4. Possible side effects

Like all medicines, Prospan® Cough Lozenges can cause side effects, although not everybody gets them.

The following frequencies are used for evaluating adverse reactions:

<b>Very common:</b>	may affect more than 1 in 10 people
<b>Common:</b>	may affect between 1 and 10 people in every 100 patients treated
<b>Uncommon:</b>	may affect between 1 and 10 people in every 1,000 patients treated
<b>Rare:</b>	may affect between 1 and 10 people in every 10,000 patients treated
<b>Very rare:</b>	may affect less than 1 in 10,000 patients treated
<b>Not known:</b>	frequency cannot be estimated from the available data

##### Possible side effects:

Allergic reactions such as shortness of breath, swelling, redness of the skin and mucosa, and itching may occur after taking medicines containing ivy. The frequency is not known. Sensitive people may develop gastrointestinal symptoms such as nausea, vomiting, and diarrhoea. The frequency is not known.

You should stop taking Prospan® Cough Lozenges permanently at the first signs of a hypersensitivity reaction.

##### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [Pharmacovigilance Department]  
Kurt-Georg-Kiesinger Allee 3, D53175 Bonn  
Website: [www.bfarm.de](http://www.bfarm.de).

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

#### 5. How to store Prospan® Cough Lozenges

 **Keep this medicine out of the sight and reach of children.**

Do not store above 25°C.

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

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

#### 6. Further information

##### What Prospan® Cough Lozenges contain

The active substance is: Ivy leaf dry 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-crystallizing) (Ph. Eur.), gum arabic, citric acid, acesulfame potassium, medium chain triglycerides, orange flavouring, menthol flavouring, purified water.

1 lozenge contains 0.53 g maltitol and 0.53 g sorbitol, equiva-

lent to approx. 0.09 carbohydrate units.  
1 lozenge contains 2.6 kcal = 10.6 kJ.

##### What Prospan® Cough Lozenges looks like and contents of the pack:

Prospan® Cough Lozenges are available in original packs with 20 (N1) lozenges.

##### Marketing Authorisation Holder and Manufacturer

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**This leaflet was last revised in November 2020.**

Note:

Prospan® Cough Lozenges contain a herbal active ingredient. This herbal extract may occasionally cause slight colour and flavour fluctuations in Prospan® Cough Lozenges. Both of these factors have no impact on the quality of the product.

