

Package leaflet: Information for the user

Prospan® Cough Syrup

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

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

Prospan® Cough Syrup are a herbal medicine for catarrhal disorders affecting the airways.

Prospan® Cough Syrup is used to alleviate the symptoms of chronic-inflammatory bronchial disorders; acute inflammations affecting the airways associated with cough.

Note:

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

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

Do not take Prospan® Cough Syrup

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

Special care with taking Prospan® Cough Syrup is required

Children:

In children under one year of age, Prospan® Cough Syrup should only be used after consulting with a doctor. The medicine should only be given to children in this age

group under careful monitoring, because children under one year must be monitored for diarrhoea and vomiting particularly carefully as compared to older children. Please also take into account the information contained in the section "Possible side effects".

Other medicines and Prospan® Cough Syrup

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 Prospan® Cough Syrup:

This medicine contains sorbitol. During each use, 1.9 g sorbitol are consumed. 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 Prospan® Cough Syrup

Always take Prospan® Cough Syrup 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:

Age	Single dose	Total daily dose
Children under 6 years of age	2.5 ml, equivalent to 17.5 mg dried ivy leaf extract	5 ml (twice 2.5 ml), equivalent to 35 mg dried ivy leaf extract
Children from 6-12 years of age	5 ml, equivalent to 35 mg dried ivy leaf extract	10 ml (twice 5 ml), equivalent to 70 mg dried ivy leaf extract
Children from 12 years of age and adults	5 ml, equivalent to 35 mg dried ivy leaf extract	15 ml (three times 5 ml), equivalent to 105 mg dried ivy leaf extract

Method of administration

To be taken orally using the included measuring cup. The liquid is taken in the morning, (around midday) and in the evening.

Shake the bottle well before any use!

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 Prospan® Cough Syrup is too strong or too weak.

If you take more Prospan® Cough Syrup than you should:

You should not take more Prospan® Cough Syrup 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 a doctor.

If you forget to take Prospan® Cough Syrup:

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 itching may occur. The frequency is unknown. In sensitive people, gastrointestinal symptoms such as nausea, vomiting, diarrhoea, as well as – due to the sorbitol content – a laxative effect may occur. The frequency is unknown.

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, D-53175 Bonn, website: 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 Syrup**Keep out of the reach and sight of children!**

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

Information regarding shelf life after opening or reconstitution:

Can be used for 6 months after opening.

6. Other information**What Prospan® Cough Syrup contains**

The active substance is: dried ivy leaf extract

100 ml liquid contain 0.7 g dried ivy leaf extract (5 - 7.5 : 1). Extracting agent: Ethanol 30% (m/m).

The other ingredients are:

potassium sorbate (Ph.Eur.) (preservative), anhydrous citric acid (Ph.Eur.), xanthan gum, flavouring, sorbitol solution 70% (crystallising) (Ph.Eur.), purified water.

2.5 ml liquid contain 0.963 g sugar substitute sorbitol (Ph. Eur.) = 0.08 bread units.

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

Prospan® Cough Syrup is available in original packs of 100 ml (N 1) and 200 ml (N 2) liquid.

Hospital pack of 1000 ml liquid (5 x 200 ml).

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in October 2018.

Notes:

Prospan® Cough Syrup contains a herbal active substance. Due to this herbal extract, there sometimes may be slight clouding and variations in taste of Prospan® Cough Syrup. Both these factors do, however, not affect the quality of the product.

