

PROSPAN®

Cough Liquid



Information for the user

Prospan® Cough Liquid

Liquid for oral use

Active ingredient: Ivy leaves dry extract

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

This medicine is also available without prescription. However, you still need to use Prospan® Cough Liquid as directed to get the best results from it.

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

In this leaflet:

1. What Prospan® Cough Liquid is and what it is used for
2. Before you take Prospan® Cough Liquid
3. How to take Prospan® Cough Liquid
4. Possible side effects
5. How to store Prospan® Cough Liquid
6. Further information

1. WHAT PROSPAN® COUGH LIQUID IS AND WHAT IT IS USED FOR

Prospan® Cough Liquid is a herbal medicine used to treat catarrhal diseases of the respiratory tract.

Prospan® Cough Liquid is used

to improve complaints of chronic-inflammatory bronchial diseases; acute inflammations of the respiratory tract accompanied by coughing.

Note:

In the event of persistent complaints or the appearance of shortness of breath, fever as well as purulent or bloody expectoration, a doctor should be consulted immediately.

2. BEFORE YOU TAKE PROSPAN® COUGH LIQUID

Do not take Prospan® Cough Liquid

if you are hypersensitive (allergic) to the active substance or any of the other ingredients of Prospan® Cough Liquid (see section 6).

Contains sorbitol

When used as directed, each dose contains 1.9 g of sorbitol. This poses a health risk to patients with a hereditary intolerance to fructose. Such patients may only take this medicine after talking to their doctor first.

Take special care with Prospan® Cough Liquid

Children

Prospan® Cough Liquid may not be used in children under the age of 6.

Taking Prospan® Cough Liquid together with other medicines

No research has been carried out. No interactions have become known so far. Please tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding

This medicine should not be used, as there have not been enough studies performed on pregnant women and mothers who breastfeed.

Driving and using machines

No special precautions are needed.

3. HOW TO TAKE PROSPAN® COUGH LIQUID

Always take Prospan® Cough Liquid exactly as described in this leaflet. You should check with your doctor or pharmacist if you are not sure.

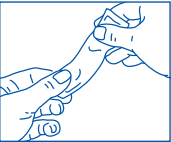
Unless otherwise prescribed by your doctor, the usual dose is:

Age	Single Dose	Total Daily Dosis
Adults and adolescents older than 12 years	5 ml (one stick pack), corresponding to 35 mg ivy leaves dry extract	15 ml (one stick pack three times daily), corresponding to 105 mg ivy leaves dry extract
Children between 6 - 11 years	5 ml (one stick pack), corresponding to 35 mg ivy leaves dry extract	10 ml (one stick pack two times daily), corresponding to 70 mg ivy leaves dry extract

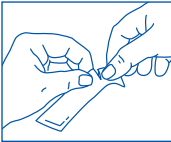
Method of use:

The liquid should be taken undiluted in the morning, (at midday) and in the evening.

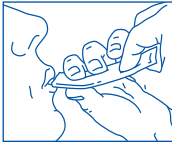
For Prospan® Cough Liquid, we have chosen to use a stick pack that can be opened easily. Its content is also easy to take. For more details on using the stick pack, please refer to the diagrams below:



Gently knead the stick pack before use, as shown.



Hold the stick pack firmly and tear it open.



Swallow the medicine, squeezing the stick pack until empty.

How long you should keep taking Prospan® Cough Liquid

Length of treatment is dependent on the nature and severity of your condition. However, even in the case of mild inflammation of the respiratory tract, treatment should last for one week at least. In the interests of ensuring that your recovery is permanent and complete, it is recommended that you should keep taking Prospan® for another 2-3 days after your symptoms have disappeared.

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

If you take more Prospan® Cough Liquid than you should

Do not exceed the recommended daily dose. Ingestion of significantly higher amounts (more than three times the daily dose) may lead to nausea, vomiting and diarrhoea. In this case you should consult a doctor.

If you forget to take Prospan® Cough Liquid

Do not take a double dose to make up for a forgotten dose. Simply continue to take Prospan® Cough Liquid as prescribed by your doctor or as directed in this leaflet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Prospan® Cough Liquid can cause side effects.

The following frequency convention is used when evaluating side effects:

Very common: more than one in 10 patients treated
Common: one to 10 in 100 patients treated
Uncommon: one to 10 in 1,000 patients treated
Rare: one to 10 in 10,000 patients treated
Very rare: less than one in 10,000 patients treated
Unknown: frequency on the basis of available data not assessable

Very rare:
Allergic reactions (shortness of breath, swelling, skin redness, itching) may occur after taking medicines containing ivy.

Uncommon:
In sensitive patients, gastrointestinal complaints may occur (nausea, vomiting and diarrhoea).

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

5. HOW TO STORE PROSPAN® COUGH LIQUID

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

Do not use Prospan® Cough Liquid after the expiry date which is stated on the outer carton and stick pack.
The expiry date relates to the last day of the month.

6. FURTHER INFORMATION

What Prospan® Cough Liquid contains:

The active ingredient is:
Ivy leaves dry extract.
5 ml of liquid (one stick pack) contain 35 mg of ivy leaves dry extract (5-7.5:1). Extractive agent: ethanol 30% (w/w).

The other ingredients are:
Potassium sorbate (Ph.Eur.) (preservative); citric acid, anhydrous (Ph.Eur.); xanthan gum; sorbitol solution 70% (crystallising) (Ph.Eur.); aromas; menthol; purified water.

5 ml of liquid (one stick pack) contain 1.926 g of sorbitol (Ph.Eur.) (sweetener) = 0.16 BU

Contents of the pack:
Prospan® Cough Liquid is available in original packs of 21 stick packs, each containing 5 ml of oral liquid.

Marketing Authorisation Holder and Manufacturer
Engelhard Arzneimittel GmbH & Co. KG
Herzbergstr. 3
D-61138 Niederdorfelden
Germany

Distributor
Please insert name and address of distributor

This leaflet was last revised in August 2007.

Note:

Prospan® Cough Liquid contains a plant-based active substance. These plant extracts can occasionally cause Prospan® Cough Liquid to become slightly cloudy or they may slightly alter its taste. However, such effects do not alter the effectiveness or quality of the product.

Plant extracts are manufactured from the dried plant, referred to as “drug”. First of all, dried ivy leaves are extracted in a mixture of water and alcohol, i.e. the ingredients are leached from the leaves. This process is known as extraction. Next follows a drying process, where the alcohol is completely removed from the extract, **leaving the preparation alcohol-free.**

An important term for describing the quality of extracts is the so-called “Drug to Extract Ratio” (DER).
A DER of 5 - 7.5 : 1 means that 5 to 7.5 parts of the drug were needed to produce one part of extract.

Dear Patient,

Therapeutic ivy - Nature's force
For hundreds of years, many people have placed their trust in the effective healing power of wild medicinal ivy for the treatment of inflammatory illnesses of the respiratory tract. *Engelhard Arzneimittel* has taken the knowledge handed down on this power of nature and has further developed it through years of intensive research. The result is an original ivy extract, which is manufactured using a special process and which can be found in all Prospan® preparations. With this extract, the pure power of medicinal ivy can be put to best use in a modern way.

Prospan® - a solution for your cough
Prospan® causes thick mucus to become liquefied, thereby making it easier to cough up. At the same time, the urge to cough is reduced. In this way, Prospan® combats the typical symptoms of bronchitis: excessive production of thick mucus, shortness of breath and the urge to cough, thereby allowing the patient to breathe freely again.

Prospan® Cough Liquid contains no alcohol or gluten. Prospan® is also available in the following forms: effervescent tablets, syrup, tablets, drops and suppositories.

You can also find further information on Prospan® at our website: <http://www.prospan.de>.

We wish you a speedy recovery.



Engelhard Arzneimittel GmbH & Co. KG
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