

Module 1.3.1 Package Leaflet

Prospan® Cough Syrup

Ivy leaf extract

Patient Information Leaflet

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 Syrup 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 or qualified healthcare practitioner 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.

What is in this leaflet:

- 1. What Prospan® Cough Syrup is and what it is used for**
- 2. 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. Further information**

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

This product is a traditional herbal medicinal product containing *ivy leaf extract*.

It is a traditional herbal medicinal product used to relieve chesty coughs associated with the common cold based on traditional use only.

2. BEFORE YOU TAKE PROSPAN® COUGH SYRUP

Do not take Prospan® Cough Syrup

- if you are allergic (hypersensitive) to the active ingredient, ivy leaf or to any of the excipients of Prospan® Cough Syrup (see section 6).
- if you are under 12 years old

Consult your doctor or qualified healthcare practitioner before taking this medicine if

- you have gastritis (inflammation of lining of stomach) or have a gastric ulcer (stomach ulcer)

- you are already taking a medicine to help stop you coughing, such as codeine or dextromethorphan.
- If you have difficulty breathing, have a fever or bloody phlegm, consult your doctor or qualified healthcare practitioner.

Taking other medicines

Studies investigating the effects of Prospan® Cough Syrup on other medicines have not been performed. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine. The safety of this product during pregnancy and breast-feeding has not been established, therefore the use of this product during pregnancy and breast-feeding is not recommended.

Important information about some of the ingredients of Prospan® Cough Syrup:

This medicine contains sorbitol. See section 6.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PROSPAN COUGH SYRUP

For oral use only.

Always take Prospan® Cough Syrup exactly as described in this leaflet.

Do not exceed the stated dose.

You should check with your doctor or pharmacist if you are not sure. Shake the bottle well each time before use.

The usual dose is:

Age	Dose
Adults, the elderly, children aged 12 years and over	5 ml three times daily

Take this product with the enclosed measuring cup.

Take one dose in the morning, at midday and in the evening.

This product is not recommended for use in children under 12 years old.

Consult your doctor or qualified healthcare practitioner if your symptoms worsen or if symptoms persist after using the product for 7 days, if shortness of breath, fever or bloody phlegm occur, if side effects listed in section 4 become serious or if side effects not listed in section 4 occur.

Duration of use

The product should not be used for more than 2 weeks.

If you take more Prospan® Cough Syrup than you should

If you take more than the recommended dose (more than three times the daily dose), you may experience nausea, diarrhoea, vomiting or feel excitable. In this case speak to your doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product

Do not take twice the dose but continue to take the usual dose at the usual time.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this product may have side-effects, although not everybody gets them.

They are listed below.

Allergic reactions, such as skin rash, red itchy skin and shortness of breath; gastrointestinal disorders such as nausea, vomiting and diarrhoea have been reported. There may be a laxative effect due to the ingredient sorbitol.

The frequency is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or qualified healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call free phone 0800 100 3352 (available 10am – 2pm Monday – Friday).

5. HOW TO STORE PROSPAN® COUGH SYRUP

Keep all medicines out of the reach and sight of children.

Do not use Prospan® Cough Syrup after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

After the first opening of the bottle, the product must be used within 3 months.

6. FURTHER INFORMATION

This product is a traditional herbal medicinal product containing *ivy leaf extract*.

Active ingredient: Each 5 ml of syrup contains 35 mg of extract (as dry extract) from ivy leaf (*Hedera helix* L.) (5 - 7.5 : 1).

Extraction solvent: ethanol 30 % w/w.

This product also contains the following ingredients:

Potassium sorbate

Anhydrous citric acid

Xanthan gum

Cherry flavour

Sorbitol liquid 70% (crystallising)

Purified water.

Each 5 ml of syrup contains 1926 mg sorbitol.

Prospan® Cough Syrup is a light brown, slightly cloudy syrup. It contains a plant extract as the active ingredient and its colour and taste can therefore occasionally vary. This, however, does not affect the quality of the preparation.

Each pack contains 100 or 200 ml of syrup.

Not all pack sizes may be marketed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

Registration holder and manufacturer of the product:

ENGELHARD Arzneimittel GmbH & Co. KG

Herzbergstrasse 3

D-61138 Niederdorfelden, Germany

Telephone: +49 (0) 6101 539-300

Email: info@engelhard.de

Traditional herbal registration number: THR 35693/0001

For blind people or partially sighted the XPIL services can be used at <http://xpil.medicines.org.uk/>.

If you would like further information about this product, please contact:

ENGELHARD Arzneimittel GmbH & Co. KG

Herzbergstrasse 3

D-61138 Niederdorfelden, Germany

Telephone: +49 (0) 6101 539-300

Email: info@engelhard.de

This leaflet was prepared 06/2015.

Please note:

font type: Frutiger 77 Black, Frutiger 67 bold condensed, Frutiger 47 light condensed, Frutiger 47 light condensed italic

font size:

text: 9 points, 10.5 points line spacing

headings: 10.5 points; 13 points, 32 points