

Package Leaflet: Information for the user

Prospan syrup

Ivy leaf dry extract

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms do not improve within 7 days or even worsen.

What is in this leaflet:

1. What Prospan syrup is and what it is used for
2. Before you take Prospan syrup
3. How to take Prospan syrup
4. Possible side effects
5. How to store Prospan syrup
6. Contents of the pack and other information

1. What Prospan syrup is and what it is used for

Prospan syrup is an herbal medicinal product.

It is an expectorant and helps release and elimination of adhered mucus.

2. Before you take Prospan syrup

Do not take Prospan syrup

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

The use of this product in children below 2 years is not recommended due to the risk of abnormal swallowing of sputum that may lead to dyspnoea as well as because vomiting and diarrhoea may occur more frequently in this age group.

In children below 4 years, it should only be used with medical supervision and in children below 12 years, it should only be used under the supervision of an adult.

Warnings and precautions

It should be used with caution in patients with gastritis or gastric ulcer.

In case of persistent symptoms, shortness of breath, fever or sputum containing pus or blood, you should contact your doctor immediately.

Other medicines and Prospan syrup

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

No drug interaction studies were performed.

Concomitant use with other expectorants such as codeine or dextromethorphan without medical supervision is not recommended.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. No clinical trials have been conducted in pregnant and breastfeeding mothers and therefore the use of this medicinal product during pregnancy and breastfeeding is not recommended.

Driving and using machines

Prospan syrup has no effect on the ability to drive vehicles and to use machines.

Prospan syrup contains sorbitol

5mL Prospan syrup contains 1.926g = 0.16BU (bread unit) sorbitol instead of sucrose.

This product should not be used in patients with rare, hereditary fructose intolerance.

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

3. How to take Prospan syrup

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose:

Age	Single dose	Daily dose
Adults and children 12 years of age and over	5-7.5mL	3 x 5-7.5mL
Schoolchildren (6 to 12 years)	5mL	3 x 5mL
Children between 2-6 years of age	2.5mL	2 x 2.5mL

Mode of administration

For accurate dosing please use the enclosed measuring cup.

Doses are recommended to be taken in the morning, (at midday) and in the evening.

Shake the bottle well before use!

Duration of treatment

The duration of therapy depends on the severity of the condition but the treatment should be continued for at least 1 week even in milder inflammations of the respiratory tract.

After cessation of symptoms, the treatment should be continued for at least additional 2-3 days.

If you take more Prospan syrup than you should

In such cases consult your doctor.

You should not take more Prospan syrup than it is indicated in the dosing table or as instructed by your doctor. In case of administration of substantially large doses (more than 3 times the daily dose), it may cause nausea, vomiting and diarrhoea.

If you forget to take Prospan syrup

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Possible side effects:

Very rare (affecting less than 1 in 10,000 patients): allergic reactions such as shortness of breath, swelling, redness of skin, feeling of itching, gastrointestinal problems such as nausea, vomiting, diarrhoea due to the sorbitol content.

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 national reporting system listed in [Appendix V](#).

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

5. How to store Prospan syrup

Keep out of the reach and sight of children.

Store below 25 °C.

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

In-use stability: 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prospan syrup contains

- The active substance:

1mL product contains:

7.00 mg of dry extract from ivy leaf (*Hedera helix* L. leaf) (5-7.5:1)

Extraction solvent: ethanol 30% w/w.

- *The other ingredients:* Potassium sorbate, anhydrous citric acid, xanthan gum, cherry flavour, crystallizing sorbitol syrup 70%, purified water.

What Prospan syrup looks like and contents of the pack

In brown bottle sealed with a pouring insert with transparent LDPE narrowing linin and white safety polyethylene screw cap and transparent polypropylene measuring cup with 2.5, 5, 7.5, and 10mL scale, in carton.

Pack size: 100mL, 200mL

Marketing Authorisation Holder and Manufacturer

Engelhard Arzneimittel GmbH & Co. KG.

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Germany

OGYI-T-21292/01 1 x 100mL

OGYI-T-21292/03 1 x 200mL

This leaflet was last revised in December 2017