

Package Leaflet: Information for the user

Prospan oral drops solution

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

1. What Prospan oral drops solution is and what it is used for

Prospan oral drops solution is an herbal medicinal product.

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

2. Before you take Prospan oral drops solution

Do not take Prospan oral drops solution

- if you are allergic to the active substance or any of the other ingredients of this medicinal product (listed in section 6) (e.g. caraway, anise, peppermint oil).
- During drug therapy where alcohol consumption is prohibited and alcohol withdrawal therapy.
- Below 12 years of age due to its alcohol content.

Warnings and precautions

During the use of Prospan oral **drops** solution, patients should contact their doctor immediately if their condition does not improve within a week or in case of persistent symptoms, shortness of breath, fever or sputum containing pus or blood.

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

Other medicines and Prospan oral drops solution

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. Concomitant use with narcotics (certain hypnotic and anaesthetic agents) is not recommended.

Pregnancy and lactation

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

Driving and using machines

Due to its alcohol content **Prospan oral drops solution** may affect the ability to drive vehicles and use machines.

Prospan oral drops solution contains ethanol

This product contains ethanol 47% v/v (alcohol) (up to 240–320 mg per dose equivalent to 5–6.5mL beer, 2–2.7mL wine). In case of alcohol problems the product is harmful. Consideration should be given to the use of this product in pregnant or breastfeeding women and high-risk patients (e.g. liver disease or epilepsy).

3. How to take Prospan oral drops solution

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 recommended dose of this product:

For children over 12 years 3x15 drops daily, for adults 3-5x20 drops daily.
Drops should 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 oral drops solution than you should

In such cases consult your doctor.

Do not take more Prospan oral drops solution than the recommended dose or as instructed 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 oral drops solution

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.

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 oral drops solution

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 bottle label. The expiry date refers to the last day of that month.

In-use stability: 6 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 oral drops solution contains

- The active substance:

1mL medicine contains:

20mg of dry extract from ivy leaf (*Hedera helix* L. leaf) (5-7.5:1)

Extraction solvent: ethanol 30% w/w.

1mL solution equal to 30 drops.

The medicine contains ethanol 47% v/v.

- *The other ingredients:* Saccharine sodium, anise oil, bitter sweet fennel, peppermint oil, ethanol (96%), purified water.

What Prospan oral drops solution looks like and contents of the pack

Dark brown liquid with alcohol and sweet fennel odour that may occasionally be cloudy, contain dark particles and/or precipitate.

Container sealed with white polyethylene applicator and white polypropylene cap, in brown carton.

The medicine is available in a pack size of 20mL.

Marketing Authorisation Holder and Manufacturer

Engelhard Arzneimittel GmbH & Co. KG.

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Germany

OGYI-T-21292/02 1x 20 ml

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