

PROSPAN®

Cough Drops

Package leaflet: Information for the user

Prospan® Drops

Oral liquid

Active ingredient: Ivy leaf dry extract

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

This medicine is available without a prescription. However, you still need to use Prospan® Drops as described in this leaflet to get the best possible results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if your symptoms get worse or do not improve after 7 days.
- If any of the listed side effects get 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® Drops are and what they are used for
2. What you need to know before you use Prospan® Drops
3. How to take Prospan® Drops
4. Possible side effects
5. How to store Prospan® Drops
6. Contents of the pack and other information

1. What Prospan® Drops are and what they are used for

Prospan® Drops are a herbal medicine for diseases of the respiratory tract involving catarrh.

Prospan® Drops are used to alleviate the symptoms of chronic inflammatory bronchial diseases, as well as acute inflammation of the respiratory tract with accompanying cough.

Note:

Medical attention should be sought immediately in case of prolonged, persistent symptoms, or in the event of shortness of breath, fever, or purulent or bloody sputum.

2. What you need to know before you use Prospan® Drops

Do not use Prospan® Drops:

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of this medicine.
- If your doctor has strictly prohibited the ingestion of minimal quantities of alcohol (e.g., after an alcohol rehabilitation programme).

Children under 1 year of age should not take Prospan® Drops.

Specific caution is required when taking Prospan® Drops:

Other medicines and Prospan® Drops:

No studies have been conducted. No interactions are known to date. Tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines. This includes medicines obtained without a prescription.

Pregnancy and breast-feeding:

As no studies have been conducted during pregnancy and breast-feeding, the medicine should only be used after consulting a doctor.

Driving and using machines:

No specific precautions are required.

Important information about some of the ingredients of Prospan® Drops:

This medicine contains 47% v/v alcohol.

3. How to take Prospan® Drops

Always take Prospan® Drops exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure. Unless otherwise prescribed by your doctor, the usual dosage is:

| Age | Single dose | Total daily dose |
|---------------------------------------|--|---|
| For adults and children from 10 years | 24 drops, equivalent to 16.8 mg ivy leaf dry extract | 72 drops (3 x 24 drops), equivalent to 50.4 mg ivy leaf dry extract |
| Children (4-10 years) | 16 drops, equivalent to 11.2 mg ivy leaf dry extract | 48 drops (3 x 16 drops), equivalent to 33.6 mg ivy leaf dry extract |
| Children (1-4 years) | 12 drops, equivalent to 8.4 mg ivy leaf dry extract | 36 drops (3 x 12 drops), equivalent to 25.2 mg ivy leaf dry extract |

Method of administration:

The liquid should be taken before food every morning, midday and evening.

Duration of use:

The duration of treatment depends on the type and severity of the symptoms; however, even in the case of mild inflammation of the respiratory tract, the drops should be used for at least 1 week.

In the interest of lasting injury treatment success, we also recommend that you continue treatment with the product for a further 2-3 days after the symptoms have resolved.

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

If you take more Prospan® Drops than you should:

You should not take more Prospan® Drops per day than stated in the dosage instructions or than prescribed by your doctor. Taking much larger quantities (more than three times the daily dose) can cause nausea, vomiting and diarrhoea. In this case, you should consult your doctor.

If you forget to take Prospan® Drops:

Do not take a double dose to make up for a forgotten dose; instead, continue taking the medicine as prescribed by your doctor or as described in the package leaflet.

4. Possible side effects

Like all medicines, Prospan® Drops can cause side effects, although not everybody gets them.

The following frequencies are used for evaluating side effects:

| |
|--|
| Very common: may affect more than 1 in 10 people |
| Common: may affect between 1 and 10 people in every 100 patients treated |
| Uncommon: may affect between 1 and 10 people in every 1,000 patients treated |
| Rare: may affect between 1 and 10 people in every 10,000 patients treated |
| Very rare: may affect less than 1 in 10,000 patients treated |
| Not known: frequency cannot be estimated from the available data |

Possible side effects:

In very rare cases, allergic reactions such as shortness of breath, swelling, skin rash and itching may occur after taking medicines containing ivy. Sensitive people may very rarely develop gastrointestinal symptoms such as nausea, vomiting, and 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 Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [Pharmacovigilance Department]
Kurt-Georg-Kiesinger Allee 3, D53175 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® Drops

 **Keep this medicine out of the sight and reach 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.

Information about shelf life after first opening or preparation:

6 months

6. Contents of the pack and other information

What Prospan® Drops contain

The active substance is: Ivy leaf dry extract

100 ml of liquid contains 2 g of ivy leaf dry extract (5 - 7.5 : 1). Extracting agent: Ethanol 30% (m/m). 1 ml of fluid is the same as 29 drops.

The other ingredients are:

Saccharin sodium, anise oil, bitter fennel oil, peppermint oil, ethanol 96%, purified water.

What Prospan® Drops looks like and contents of the pack:

Prospan® Drops are available in original packs with 20 mL (N1), 50 mL (N2) and 100 mL (N3) of liquid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Engelhard Arzneimittel GmbH & Co. KG
Herzbergstr. 3
61138 Niederdorfelden
Tel.: +49 6101 / 539 - 300
Fax: +49 6101 / 539 - 315
Website: <http://www.engelhard-am.de>
Email: info@engelhard-am.de

This leaflet was last revised in July 2021.

Note:

Prospan® Drops contain a herbal active ingredient. This plant extract may form dark particles in the liquid; the flavour of the product may also vary slightly. Both of these factors have no impact on the quality of the product.



ENGELHARD