

Package leaflet: Information for the user

Prospan® Cough Drops

Oral liquid

Active substance: dried ivy leaf extract

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

This medicine is available without prescription. In order to achieve the best possible treatment outcome, however, Prospan® Cough Drops must be used in line with the instructions.

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

What is in this leaflet:

1. What Prospan® Cough Drops are and what they are used for
2. What you need to know before you take Prospan® Cough Drops
3. How to take Prospan® Cough Drops
4. Possible side effects
5. How to store Prospan® Cough Drops
6. Other information

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

Prospan® Cough Drops are a herbal medicine for catarrhal disorders affecting the airways.

Prospan® Cough Drops are used to alleviate the symptoms of chronic-inflammatory bronchial disorders; acute inflammations affecting the airways associated with cough.

Note:

If your symptoms persist, or if you experience trouble breathing, fever or purulent or bloody discharge, you should immediately consult a doctor.

2. What you need to know before you take Prospan® Cough Drops

Do not take Prospan® Cough 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 consumption of even extremely small amounts of alcohol (e.g. after withdrawal/rehab).

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

Special care with taking Prospan® Cough Drops is required:

Other medicines and Prospan® Cough Drops:

No studies have been performed. So far, no interactions have become known. Tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including over-the-counter medicines.

Pregnancy and breast-feeding

As no studies during pregnancy and while breast-feeding are available, the medicine should only be used after consulting with a doctor.

Driving and using machines:

No special precautions are necessary.

Important information about specific other ingredients of Prospan® Cough Drops:

This medicine contains 47 vol. % alcohol!

3. How to take Prospan® Cough Drops

Always take Prospan® Cough Drops exactly as instructed in this leaflet.

Check with your doctor or pharmacist if you are not sure. Unless otherwise prescribed by a doctor, the usual dose is:

Age	Single dose	Total daily dose
Adults and adolescents from 10 years of age	24 drops, equivalent to 16.8 mg dried ivy leaf extract	72 drops (3 times 24 drops), equivalent to 50.4 mg dried ivy leaf extract
Children (4-10 years of age)	16 drops, equivalent to 11.2 mg dried ivy leaf extract	48 drops (3 times 16 drops), equivalent to 33.6 mg dried ivy leaf extract
Children (1-4 years of age)	12 drops, equivalent to 8.4 mg dried ivy leaf extract	36 drops (3 times 12 drops), equivalent to 25.2 mg dried ivy leaf extract

Method of administration

The liquid should be taken in the morning, around mid-day and in the evening before meals.

Duration of use

Treatment duration depends on the type and severity of the illness, but should usually be at least 1 week, even in case of minor inflammations of the airways.

In the interest of a sustained success of treatment, it is furthermore recommended to continue treatment with the product for 2-3 days after the signs of illness have resolved.

Please talk to your doctor or pharmacist if you feel that the effect of Prospan® Cough Drops is too strong or too weak.

If you take more Prospan® Cough Drops than you should:

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

If you forget to take Prospan® Cough Drops:

Do not take the double dose the following time, but continue intake as prescribed by the doctor or described in the package leaflet.

4. Possible side effects

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

The classification of side effects is based on the following frequencies:

Very common: more than 1 in 10 treated persons
Common: 1 to 10 in 100 treated persons
Uncommon: 1 to 10 in 1,000 treated persons
Rare: 1 to 10 in 10,000 treated persons
Very rare: less than 1 in 10,000 treated persons
Not known: The frequency cannot be estimated from the available data

Possible side effects:

After taking medicines containing ivy, allergic reactions such as trouble breathing, swelling, reddening of skin and itching may very rarely occur. In sensitive people, gastrointestinal symptoms such as nausea, vomiting, diarrhoea may occur very rarely.

5. How to store Prospan® Cough Drops

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 the container (label). The expiry date refers to the last day of that month.

Information regarding shelf life after opening or reconstitution:

6 months

6. Other information

What Prospan® Cough Drops contain

The active substance is: dried ivy leaf extract 100 ml liquid contain 2 g dried ivy leaf extract (5 - 7.5 : 1).
Extracting agent: Ethanol 30% (m/m). 1 ml liquid is equivalent to 29 drops. The other ingredients are: saccharin sodium, aniseed oil, bitter fennel oil, peppermint oil, ethanol 96%, purified water.

What Prospan® Cough Drops look like and contents of the pack:

Prospan® Cough Drops are available in original packs of 20 ml (N 1) and 50 ml (N 2) liquid.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in October 2018.

Notes:

Prospan® Cough Drops contain a herbal active substance. Due to this herbal extract, dark particles may form in the liquid; furthermore, the taste may vary slightly. Both these factors do, however, not affect the quality of the product.

