

## Package leaflet: Information for the user

### Prosparan® Cough Effervescent Tablets

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

#### 1. What Prosparan® Cough Effervescent Tablets are and what they are used for

Prosparan® Cough Effervescent Tablets are a herbal medicine for catarrhal disorders affecting the airways.

Prosparan® Cough Effervescent Tablets are used as an expectorant product to treat productive 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 Prosparan® Cough Effervescent Tablets

##### Do not take Prosparan® Cough Effervescent Tablets

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of this medicine.
- If you suffer from a fructose intolerance, treatment should only take place after consulting a doctor.

Special care with taking Prosparan® Cough Effervescent Tablets is required:

##### Children:

Prosparan® Cough Effervescent Tablets are not intended to be taken by children under 6 years of age.

### Other medicines and Prosparan® Cough Effervescent Tablets

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

Due to insufficient studies, the medicine should not be used during pregnancy and while breast-feeding.

### Driving and using machines:

No special precautions are necessary.

### Important information about specific other ingredients of Prosparan® Cough Effervescent Tablets:

One effervescent tablet contains 6.58 mmol (or 151.33 mg) sodium. If you are following a low-sodium diet, you must take this into account. The flavouring contains lactose. 1 effervescent tablet contains 29.7 mg lactose.

Therefore, if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

### 3. How to take Prosparan® Cough Effervescent Tablets

Always use Prosparan® Cough Effervescent Tablets 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 12 years of age	In the morning: 1 effervescent tablet, equivalent to 65 mg dried ivy leaf extract In the evening: ½ effervescent tablet, equivalent to 32.5 mg dried ivy leaf extract	1 effervescent tablet once and ½ effervescent tablet once, equivalent to 97.5 mg dried ivy leaf extract
Children from 6–12 years of age	½ effervescent tablet, equivalent to 32.5 mg dried ivy leaf extract	½ effervescent tablet twice, equivalent to 65 mg dried ivy leaf extract

### Method of administration

Effervescent tablets for oral use after being dissolved.

The effervescent tablets can be divided.

The effervescent tablets are taken in the morning and evening after being dissolved in a glass of water (approx. 100–200 ml). Both hot and cold water can be used to dissolve the tablet.

### Duration of use

Treatment duration depends on the type and severity of the illness; it should usually be 1 week. Should the symptoms, however, persist for longer than 1 week, medical advice should be sought.

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

### If you take more Prosparan® Cough Effervescent Tablets than you should:

You should not take more Prosparan® Cough Effervescent Tablets 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 Effervescent Tablets:**

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:

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

#### **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 occur. The frequency is unknown.

In sensitive people, gastrointestinal symptoms such as nausea, vomiting, diarrhoea may occur. The frequency is unknown.

#### **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, D-53175 Bonn, website: [www.bfarm.de](http://www.bfarm.de).

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

#### **5. How to store Prospan® Cough Effervescent Tablets**

##### **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 film strip. The expiry date refers to the last day of that month.

#### **6. Other information**

##### **What Prospan® Cough Effervescent Tablets contain**

The active substance is: dried ivy leaf extract 1 effervescent tablet contains 65 mg dried ivy leaf extract (5 – 7.5 : 1). Extracting agent: Ethanol 30 % (m/m).

##### **The other ingredients are:**

anhydrous citric acid (Ph.Eur.), sodium hydrogen carbonate, sodium carbonate, mannitol (Ph.Eur.), simethicone, saccharin sodium 2H<sub>2</sub>O, sodium cyclamate, sodium citrate 2 H<sub>2</sub>O, sorbitol (Ph.Eur.), medium-chain triglycerides, macrogolglycerol hydroxystearate (Ph.Eur.), flavouring.

1 effervescent tablet contains 382 mg carbohydrates (equivalent to 0.03 bread units).

#### **What Prospan® Cough Effervescent Tablets look like and contents of the pack:**

Prospan® Cough Effervescent Tablets are available in original packs of 20 effervescent tablets.

#### **Marketing Authorisation Holder and Manufacturer:**

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