

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Prospan® Cough Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION (Active ingredients)

100 ml solution contain 0.7 g of ivy leaves dry extract [5-7.5 : 1].

Extractive agent: ethanol 30% m/m.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a symptomatic agent in the complex treatment of inflammatory diseases of the upper respiratory tract and lungs.

4.2 Posology and method of administration

Children in age of 2-4 years take only after consultation with a doctor 2.5 ml solution 3 times daily. Children in age of 5 years take 2.5 ml solution 3 times daily.

Children aged 6 to 11 years take 5 ml solution 3 times daily, children from the age of 12 years and adults take 5-7.5 ml solution 3 times daily. Take the syrup with the enclosed measuring cup.

The syrup should be taken in the morning, (at lunchtime) and in the evening.

Duration of treatment depends on the type and severity of the symptoms, but it should last for at least one week, even in the case of minor inflammations of the respiratory tract.

To ensure success of therapy, treatment should be continued for 2-3 days after symptoms have subsided.

Shake the bottle well before every use and close it properly after use !

4.3 Contraindications

This product should not be taken by patients with known allergy to the active ingredient or to any of the excipients contained in this product.

A health risk exists in patients with congenital fructose intolerance. In this case, treatment should be carried out only after consultation with a doctor.

Children under 2 years should not take Prospan® Cough Syrup, because of the risk of exacerbation of symptoms of respiratory diseases.

4.4 Special warnings and special precautions for use

Prospan® Cough Syrup does not contain ethanol, sugar and colorant. Diabetes patients should notice that, 2.5 ml of solution contain 0.963 g of sorbitol = 0,08 BU. Ethanol is used as an absorbant for the extraction of the therapeutic extract from ivy leaves and disappears after drying.

Children in age 2-4 years should take Prospan® Cough Syrup after consultation with the doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions have not been investigated. No interactions have so far become known.

4.6 Pregnancy and lactation

As no data are available on safety during pregnancy and lactation, the preparation should not be taken during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No special precautions

4.8 Undesirable effects

- in rare cases gastrointestinal symptoms such as nausea, vomiting and diarrhoea may occur, and there may be a slight laxative effect due to the content of sorbitol.
- very rarely allergic reactions such as shortness of breath, swelling, skin redness or itching may occur
- in sensitive patients, the frequency is unknown.

4.9 Overdose

Do not exceed the recommended daily dose. Ingestion of significantly higher amounts (more than three times the daily dose) may lead to nausea, vomiting and diarrhoea.
Treat overdose symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Herbal drug for the treatment of catarrhal diseases of the respiratory tract.

ATC code:

R05CA (WHO)/R05CP02 (WiDo)

Herbal drug, which contains saponins, triterpinoids, flavonoids. Expectorant, anti cough and spasmolytic effects. Reduces the viscosity of sputum and has antimicrobial activity.

5.2 Pharmacokinetic properties

Investigations of pharmacokinetic and bioavailability data are not available.

5.3 Preclinical safety data

In tests for acute toxicity on various animal species the dry extract of ivy leaves showed no symptoms of toxicity with oral doses up to 3 g/kg body weight or subcutaneous doses up to 0.5 g/kg body weight.

In chronic toxicity studies over a period of 3 months, the dry extract of ivy leaves was administered orally to Wistar rats at a mean dose of 30-750 mg/kg body weight.

It was found that the applied doses were tolerated well and neither organ injuries nor other pathological modifications could be detected in the animals. The only difference compared with the control group was a reversible increase in haematocrit and, but only with even higher doses, a decrease in ICSH secretion.

α - hederin, β - hederin and δ - hederin isolated from ivy leaves showed no mutagenic potential in the Ames test with salmonella typhimurium TA 98, with or without activation S9.

In some tests (both in-vitro, and in-vivo) the mutagenic potential of a dry ivy leaf extract was not detected.

Studies on the toxicological effect on the reproductive function of the body or carcinogenic drugs from an extract of ivy leaves, were not carried out.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, potassium sorbate, anhydrous citric acid, xanthan gum, cherry aroma, sorbitol liquid 70% (crystallising),

2.5 ml of solution contains 0.963 g of the sugar substitute sorbitol = 0.08 BU.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years. After first opening of the container: 6 months.

6.4 Special precautions for storage

Store at a temperature not higher than 25 °C.
Keep out of the reach of children!

6.5 Nature and contents of container

100 ml in bottle. 1 bottle in the paper cartom box with measuring cap and instruction for use.

6.6 Special precautions for disposal and other handling.

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

15679

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22.02.2000
Date of latest renewal: 08.06.2016

10. DATE OF REVISION OF THE TEXT

June 2020

11. Classification

Pharmacy only medicine

