SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Prospan Cough Syrup Sachets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet (5 ml) contains 35 mg of extract (as dry extract) from ivy leaf (*Hedera helix* L.) (5-7.5:1).

Extraction solvent: ethanol 30% w/w.
For a full list of excipients, see section 6.1.
Each sachet (5 ml) contains 1926 mg sorbitol.

3 PHARMACEUTICAL FORM

Syrup

Light brown, slightly cloudy syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product used to relieve chesty coughs associated with the common cold based on traditional use only.

4.2 Posology and method of administration

For oral use only.
Massage the sachet gently before using in order to mix the contents.
Adults, the elderly, children aged 12 years and over: take one sachet (5 ml) 3 times daily.

Empty the contents of the sachet directly into the mouth.

The sachet should be taken in the morning, at middayand in the evening.

Duration of use

If symptoms worsen or persist after 7 days, a doctor or qualified healthcare pratitioner should be consulted.

The product should not be used for more than 2 weeks.

The use in children under 12 years of age is not recommended (see Section 4.4 Special warnings and precautions for use)

4.3 Contraindications

Hypersensitivity to the active ingredient, ivy leaf or to any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought.

Concomitant use with antitussives such as codeine or dextromethorphan is not recommended without medical advice.

Caution is recommended in patients with gastritis or gastric ulcer.

If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified healthcare practitioner should be consulted.
If symptoms worsen or persist for more than 7 days, a doctor or a qualified healthcare practitioner should be consulted.
Contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Allergic reactions (urticaria, skin rash, dyspnoea) and gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported.

The frequency is not known.

If other adverse side effects not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance

of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Ingestion of significantly higher amounts (more than three times the daily dose) may lead to nausea, vomiting,diarrhoea and excitation.
Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate

Anhydrous citric acid
Xanthan gum
Cherry flavour
Sorbitol liquid 70% (crystallising)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened:
3 years
Opened:
To be used immediately.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Packs with 21 sachets of 5 ml.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Engelhard Arzneimittel GmbH & co kg
Herzbergstrasse 3
Niederdorfelden
D-61138
Germany

8 MARKETING AUTHORISATION NUMBER(S)

THR 35693/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/02/2011

10 DATE OF REVISION OF THE TEXT

06/07/2015

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)