Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Herbal Chesty Coughs Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 ml of syrup contains 33 mg of extract (as dry extract) from *Hedera helix* L., folium (Ivy leaf) (DER 4-8:1). Extraction solvent ethanol 30 % m/m.

Excipient with known effect:
Each 4ml of syrup contains 2832 mg of sorbitol.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
Brown, opalescent liquid with a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used as an expectorant for the relief of chesty cough associated with the common cold, exclusively based on long standing use.

Benylin Herbal Chesty Coughs Syrup is indicated in adults and adolescents aged 12 years and over.

4.2 Posology and method of administration

Posology
Adults, the elderly, and adolescents aged 12 years and over
The recommended dose is 4 ml of syrup two to three times daily using the graduated measuring spoon provided

Paediatric population
The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).
Use in children under 2 years of age is contraindicated (see section 4.3 Contraindications).

Duration of use
If the symptoms persist, worsen or do not improve after 7 days of use of Benylin Herbal Chesty Coughs Syrup, a doctor or qualified health professional e.g. a doctor or pharmacist should be consulted.
The product should not be used for more than 2 weeks.

Method of administration
For oral short-term use only.

4.3 Contraindications

Hypersensitivity to ivy preparations or to any of the excipients listed in section 6.1, or to any other plant belonging to the family Araliaceae.

Use in children under 2 years of age is contraindicated due to the risk of exacerbations of respiratory symptoms caused by expectorants.

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.

If dyspnoea, fever or purulent sputum occurs, a doctor should be consulted.

If the symptoms worsen, or persist longer than 7 days during the use of Benylin Herbal Chesty Coughs Syrup, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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.

Paediatric population
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.
For children under 2 years of age see section 4.3.

Benylin Herbal Chesty Coughs Syrup contains sorbitol.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Each 4 ml of syrup contains 2832 mg of sorbitol (E 420).
Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, Benylin Herbal Chesty Coughs Syrup should not be used during pregnancy and lactation.

Fertility
No studies on the effect on fertility have been performed.

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

Immune System Disorders: Hypersensitivity (Urticaria, Rash, Dyspnoea). The frequency is not known (cannot be estimated from the available data)

Gastrointestinal Disorders: Nausea, Vomiting, Diarrhoea. The frequency is not known (cannot be estimated from the available data)

If other adverse reactions not mentioned above occur, a doctor or pharmacist 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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

Overdose can provoke nausea, vomiting, diarrhoea and agitation. One case of a 4-year old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding to 1.8 g herbal substance has been reported

Treatment is symptomatic.

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

Reverse mutation assays (Ames test) on bacteria indicated that the herbal preparation was not mutagenic in *Salmonella typhimurium* (strains TA 98, TA 100, TA 1535 and TA 1537) mutation assays with or without metabolic activation

Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, liquid (non-crystallising) (E 420)
Xanthan gum
Potassium sorbate
Citric acid, anhydrous
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.
Opened: 3 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
After first opening do not store above 25 °C.

6.5 Nature and contents of container

This medicinal product is available in 100 ml bottles made of brown glass. The bottles are closed with white screw caps (HDPE) with cone sealing.

The bottle is further packed into a carton together with a measuring spoon (with graduation 2 and 4 ml).

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR23490/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 15th November 2024

10 DATE OF REVISION OF THE TEXT

December 2025