

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Strepsils Herbal Chesty Cough syrup

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of the syrup contains 8.25 mg of extract (as dry extract) from *Hedera helix* L., folium (ivy leaf) (4-8:1).

Extraction solvent: ethanol 30% (m/m).

### Excipient with known effect:

Sorbitol, liquid (non-crystallising): 1 mL of syrup contains up to 496 mg of sorbitol.

This medicine contains 16.8 mg propylene glycol in each 2 ml which is equivalent to 8.4 mg/ml.

This medicine contains 0.0038 mg benzyl alcohol in each 2 ml which is equivalent to 0.0019 mg/ml.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Syrup.

The syrup is a brown, opalescent liquid with a sweet taste and possible slight sediment.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Strepsils Herbal Chesty Cough syrup is a traditional herbal medicinal product used as an expectorant in case of productive cough, exclusively based upon long-standing use.

Strepsils Herbal Chesty Cough syrup is indicated in adults and adolescents aged 12 years of age and older.

### 4.2 Posology and method of administration

#### Posology

*Adolescents from 12 years of age, adults and elderly:*

6 mL of syrup twice daily (corresponding to 99 mg of ivy leaf dry extract daily)

#### *Paediatric population*

The use in children under 12 years of age is not recommended (see section 4.4).

The use in children under 2 years of age is contraindicated (see section 4.3).

#### Patients with renal and/or hepatic impairment

Due to the lack of pharmacokinetic data in these patient groups, a dose recommendation is not possible. Patients are advised to consult their doctor before taking Strepsils Herbal Chesty Cough syrup .

#### Method of administration

For oral short-term use only.

It is recommended that the dose of 6 mL is administered with a full measuring spoon (4 mL) + half a measuring spoon (2 mL).

The bottle should be shaken well before use.

#### Duration of use

If the symptoms worsen, do not improve or persist after 7 days , a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

### 4.3 Contraindications

- Hypersensitivity to the active substance, to other plants of the *Araliaceae* (ivy) family or to any of the excipients listed in section 6.1.
- Children under 2 years of age because of the risk of aggravation of respiratory symptoms.

### 4.4 Special warnings and precautions for use

Do not exceed the stated dose.

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

Caution is recommended in patients with gastritis or gastric ulcer.

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

#### Paediatric Population

The use in children under 12 years of age is not recommended due to the lack of adequate data. For children under 2 years of age see section 4.3.

Strepsils Herbal Chesty Cough syrup contains sorbitol (E420).

This medicine contains 2976 mg sorbitol in each 6mL which is equivalent to 496mg/ml.

Patients with hereditary fructose intolerance (HFI) should not take this medicinal product.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Strepsils Herbal Chesty Cough syrup contains benzyl alcohol.

This medicine contains 0.0114 mg benzyl alcohol in each 6mL which is equivalent to 0.0019 mg/ml.

Large amounts of benzyl alcohol should be avoided due to the risk of accumulation and toxicity (metabolic acidosis) and should be used with caution in patients with impaired liver or kidney function and during pregnancy or breast feeding.

### 4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions with other drug products have been reported.

### 4.6 Fertility, pregnancy and lactation

#### Pregnancy

There are no data from the use of Strepsils Herbal Chesty Cough syrup in pregnant women. There are no reproductive toxicity studies in animals (see section 5.3). Strepsils Herbal Chesty Cough syrup is not recommended during pregnancy.

#### Breast-feeding

It is unknown whether the active substance or its metabolites are excreted into human breast milk. A risk to the breastfed newborn / child cannot be excluded. Strepsils Herbal Chesty Cough syrup should not be used during breast-feeding.

#### Fertility

There are no data on the effects of Ivy leaf dry extract on fertility available.

### 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

Undesirable effects that may occur during treatment with Strepsils Herbal Chesty Cough syrup are classified into the following groups in order of frequency:

- Very common (1/10)
- Common (1/100, <1/10)
- Uncommon (1/1,000, <1/100)
- Rare (1/10,000, <1/1,000)
- Very rare (<1/10,000)

	Common	Uncommon
Immune system disorders		<u>Urticaria</u> <u>Skin rash</u> <u>Dyspnoea</u> <u>Anaphylactic reaction</u>
Gastrointestinal disorders	<u>Nausea</u> <u>Vomiting</u> <u>Diarrhoea</u>	

If severe undesirable effects occur, treatment should be discontinued.

If other adverse reactions not mentioned above occur, a doctor or a 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 HPRC Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie).

#### **4.9 Overdose**

Intake of doses larger than those recommended can provoke nausea, vomiting, diarrhoea and agitation. Treatment is symptomatic.

A case of an overdose has been reported in a 4 year old child. Following an accidental ingestion of a large amount of ivy extract (corresponding to 1.8 g of ivy leaf, which approximately amounts to 36 mL of Strepsils Herbal Chesty Cough syrup, aggressiveness and diarrhoea occurred.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Cough and cold preparations, Expectorants. ATC code: R05CA12.

Strepsils Herbal Chesty Cough syrup is a Traditional herbal medicinal product.  
No relevant pharmacodynamic data is available.

#### **5.2 Pharmacokinetic properties**

No pharmacokinetic studies have been performed.

#### **5.3 Preclinical safety data**

The non-clinical data on Ivy leaf dry extract are incomplete. In a bacterial reverse mutation test (AMES test), no mutagenic effects of the Ivy leaf dry extract contained in Strepsils Herbal Chesty Cough syrup were detected. Studies on carcinogenicity and reproductive toxicity of Ivy leaf dry extract have not been performed.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Sorbitol liquid (non-crystallising) (E420)  
Potassium sorbate (E202)

Xanthan gum (E415)  
Citric acid (E330)  
Natural honey thyme flavour (contains:  
Propylene glycol (E1520),  
Benzyl alcohol (E 1519))  
Purified water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

Originally sealed package: 2 years  
After first opening: 3 months

## **6.4 Special precautions for storage**

This medicinal product does not require any storage conditions in the originally sealed package.  
Do not store above 25°C after first opening.

## **6.5 Nature and contents of container**

Brown glass bottle with white screw cap (HDPE). The bottle is packed into a carton together with a measuring spoon (PP) with graduations of 2 and 4 mL.  
Pack size: 100 mL.

## **6.6 Special precautions for disposal**

No special requirements for disposal.

## **7 REGISTRATION HOLDER**

Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24.

## **8 REGISTRATION NUMBER(S)**

TR0979/087/001

## **9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

Date of first registration: 6<sup>th</sup> March 2026

## **10 DATE OF REVISION OF THE TEXT**