

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Herbal Dry Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml (corresponding to 1.2 g) of the syrup contains 30 mg of extract (as dry extract) from *Plantago lanceolata* L. s.l., folium (*Ribwort plantain*) (DER 3-5:1).

Extraction solvent: ethanol 20 % (m/m).

Excipients with known effect:

10 ml contains 6640 mg maltitol liquid (containing maltitol and up to 450 mg sorbitol).

10 ml contains 112 mg natural flavour which contains less than 1 % sucrose.

This medicine contains 78.5 mg of alcohol (ethanol) in each dosage unit of 10 ml which is equivalent to 7.85 mg/ml (0.785 % (w/v)).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

Brown liquid with characteristic odour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Strepsils Herbal Dry Cough Syrup is a traditional herbal medicinal product used for the symptomatic treatment of throat irritation and associated dry cough, exclusively based upon long-standing use.

Strepsils Herbal Dry Cough Syrup is indicated in adults and adolescents aged 12 years and older.

4.2 Posology and method of administration

Posology

Adults, elderly and adolescents from 12 years of age:

10 ml of syrup three to four times a day.

Paediatric Population

Children under 12 years of age

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

Patients with renal and/or hepatic impairment

Due to the lack of pharmacokinetic data in these patient groups, a dose recommendation is not possible.

Method of administration

Oral use.

For correct dosing the enclosed measuring spoon should be used, applying the 5ml graduated mark twice, for a 10ml dose.

The bottle should be shaken before use.

Duration of use

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

For oral short-term use only.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the symptoms worsen during the use of the medicinal product or if dyspnoea, fever or purulent sputum occurs, a doctor should be consulted.

Paediatric Population

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

Strepsils Herbal Dry Cough Syrup contains maltitol liquid (containing maltitol and sorbitol). This medicine contains up to 450 mg sorbitol in each 10 ml which is equivalent to 45 mg/ml. 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.

Patients with hereditary fructose intolerance (HFI), glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take or be given this medicinal product.

May have a mild laxative effect.

Calorific value 2.3 kcal/g of maltitol liquid.

Strepsils Herbal Dry Cough Syrup contains ethanol.

This medicine contains 78.5 mg of alcohol (ethanol) in each 10 ml which is equivalent to 7.85 mg/ml (0.785 % (w/v)). The amount in 10 ml of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of ribwort plantain leaf dry extract in pregnant women. Animal studies are insufficient with respect to developmental toxicity. Strepsils Herbal Dry Cough Syrup is not recommended during pregnancy.

Breast-feeding

It is unknown whether the active substances or metabolites are excreted in human breast milk. A risk to the breastfed newborn / child cannot be excluded. Strepsils Herbal Dry Cough Syrup should not be used during breast-feeding.

Fertility

There are no data on the effects 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

None known.

If adverse reactions occur, a doctor or a pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after registration of the traditional herbal medicinal product is important. It allows continued monitoring of the safety of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system see HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

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

In a bacterial reverse mutation test (AMES test) on 5 Salmonella typhimurium strains, no relevant mutagenic potential of dry extract from Plantago lanceolata L., folium, has been detected.
Studies on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin
Maltitol liquid (E 965) (contains maltitol and sorbitol)
Xanthan gum (E 415)
Potassium sorbate (E 202)
Citric acid (E 330)
Natural flavour Honey-Lemon-Verbena (contains ethanol and sucrose)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Store below 25°C after first opening.
A sediment may occur during storage. This does not affect the quality of the product.

6.5 Nature and contents of container

Amber glass bottle with polyethylene screw cap.
The bottle is further packed into folding boxes with a patient information leaflet and a polypropylene measuring device.
The measuring spoon shows 5ml graduated mark to be taken twice, for a 10ml dose.
Pack sizes 100 ml and 200 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 REGISTRATION HOLDER

Reckitt Benckiser Ireland Limited
7 River Walk
Citywest Business Campus
Dublin 24
D24 H2CE
Ireland

8 REGISTRATION NUMBER(S)

TR0979/088/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

10 DATE OF REVISION OF THE TEXT