

## **Package leaflet: Information for the patient**

### **Strepsils Herbal Dry Cough Syrup**

Ribwort plantain dry extract

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **What is in this leaflet**

1. What Strepsils Herbal Dry Cough Syrup is and what it is used for
2. What you need to know before you take Strepsils Herbal Dry Cough Syrup
3. How to take Strepsils Herbal Dry Cough Syrup
4. Possible side effects
5. How to store Strepsils Herbal Dry Cough Syrup
6. Contents of the pack and other information

#### **1. What Strepsils Herbal Dry Cough Syrup is and what it is used for**

Strepsils Herbal Dry Cough Syrup is a traditional herbal medicinal product used to relieve symptoms 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.

You must talk to a doctor if you feel worse during use or do not feel better after 7 days.

#### **2. What you need to know before you take Strepsils Herbal Dry Cough Syrup**

##### **Do not take Strepsils Herbal Dry Cough Syrup:**

- if you are allergic to ribwort plantain or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Contact your doctor immediately if your symptoms worsen, you experience shortness of breath, fever or purulent mucus (yellowish phlegm) during the use of this medicine.

##### **Use in patients with impaired renal and/or liver function**

If you suffer from renal insufficiency or hepatic impairment, please talk to your doctor or pharmacist before taking Strepsils Herbal Dry Cough Syrup.

## **Children**

The use of Strepsils Herbal Dry Cough Syrup in children under 12 years of age is not recommended due to the lack of adequate data.

## **Other medicines and Strepsils Herbal Dry Cough Syrup**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Pregnancy

The safety of taking this medicine during pregnancy is not known. Therefore, it is not recommended to take this medicine if you are pregnant.

### Breast-feeding

It is unknown whether the active substance or its metabolites are excreted into human milk. A risk to the breast-fed newborn/infant cannot be excluded. Strepsils Herbal Dry Cough Syrup should therefore not be used during breast-feeding.

## **Driving and using machines**

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

## **Strepsils Herbal Dry Cough Syrup contains maltitol liquid (containing maltitol and sorbitol)**

This medicine contains up to 450 mg sorbitol in each 10 ml dose which is equivalent to 45 mg/ml. Sorbitol is a source of fructose.

If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

May have a mild laxative effect. Calorific value 2.3 kcal/g of maltitol liquid.

## **Strepsils Herbal Dry Cough Syrup contains ethanol (alcohol)**

This medicine contains 78.5 mg of alcohol (ethanol) in each 10 ml dose 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.

## **3. How to take Strepsils Herbal Dry Cough Syrup**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For oral short-term use only.

The recommended dose is:

*Adults, elderly and adolescents from 12 years of age:*  
10 ml of syrup three to four times a day.

### **Use in children**

The use of Strepsils Herbal Dry Cough Syrup in children under 12 years of age is not recommended.

### **Use in patients with impaired renal and/or liver function**

Please refer to section 2.

### **Method of administration**

Oral use.

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

Shake the bottle well before every use.

### **Duration of use**

You must talk to a qualified healthcare professional e.g. a doctor or pharmacist if you do not feel better, if you feel worse or if the symptoms don't resolve after 7 days.

### **If you take more Strepsils Herbal Dry Cough Syrup than you should**

Talk to a doctor straight away, or contact your nearest hospital casualty department. Take the carton and this leaflet with you.

### **If you forget to take Strepsils Herbal Dry Cough Syrup**

Do not take a double dose to make up for a forgotten dose. Take the next recommended dose as required.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

However no side effects have been reported for this medicine.

If adverse reactions occur, a doctor should be consulted.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Strepsils Herbal Dry Cough Syrup**

Keep this medicine out of the sight and reach of children.

A sediment may occur during storage. This does not affect the quality of the product.

This medicine does not require any special storage conditions.  
Store below 25°C after first opening.

Do not use this medicine after the expiry date which is stated on the carton and the bottle. The expiry date refers to the last day of that month.

Do not use after 3 months from first opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Strepsils Herbal Dry Cough Syrup contains**

- The active substance is ribwort plantain dry extract. Each ml (corresponding to 1.2 g) of 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).
- The other ingredients are: 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) and purified water.

### **What Strepsils Herbal Dry Cough Syrup looks like and contents of the pack**

The syrup is a brown liquid with a characteristic odour packed in bottles of 100 or 200 ml volume. The bottle is further packed into folding boxes with a patient information leaflet and a measuring device. The measuring spoon shows a 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.

### **Registration Holder**

Reckitt Benckiser Ireland Ltd  
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### **Manufacturer**

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Traditional herbal registration number: TR 0979/088/001

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