

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Lemsip Cough for Dry Cough & Sore Throat Oral Solution

Strepsils Sore Throat & Dry Cough Syrup

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Quantity/dose	Specification
Glycerol	0.25 ml	EP
Honey	500.00 mg	HSE
Citric acid monohydrate	25.00 mg	EP
Lemon oil terpeneless	0.0005 ml	BP
Syrup	3.75ml	BP

#### Excipient(s) with known effect:

- Sodium – 0.832 mg /5ml dose
- Ethanol – 37.865 mg (0.048 ml) /5ml dose
- Benzyl Alcohol\* (\*trace amounts present in Lemon Oil Terpeneless)
- Parahydroxybenzoates and their esters\* (\*nipasept sodium contains sodium ethyl p-hydroxybenzoate (E215), sodium propyl p-hydroxybenzoate and sodium methyl p-hydroxybenzoate (E219))

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Oral syrup.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the symptomatic relief of dry tickly coughs and sore throats.

#### 4.2 Posology and method of administration

Route of administration - oral.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms and a healthcare professional should be consulted if symptoms persist or worsen.

No special dose is required for elderly patients.

Glass bottle

Adults and children 12 years and over: Two 5ml spoonfuls, three or four times daily.

Children 1-12 years: One 5ml spoonful, three or four times daily.

#### PETE plastic bottle

Adults and children 12 years and over: 10 ml dose (fill measure cup to 10 ml), three to four times daily.

Children aged 1-12 years: 5 ml dose (fill measure cup to 5 ml), three to four times daily.

Rinse the measure cup after use.

### **4.3 Contraindications**

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

Do not give to children under 1 year.

### **4.4 Special warnings and precautions for use**

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

The product may contain sufficient amounts of sugar to affect the control of diabetes.

This medicine contains 0.04 mg alcohol (ethanol) in each 5ml dose. The amount in a 5 ml dose of this medicine is equivalent to less than 1 ml of beer or 1 ml of wine.

This medicine contains trace amounts of benzyl alcohol in each 5ml dose. Benzyl alcohol may cause allergic reactions.

Contains esters of parahydroxybenzoic acid which may cause allergic reactions (possibly delayed).

Citrates should not be taken together with aluminium hydroxide or aluminium-containing antacids in patients with end stage renal disease unless consulted with health care professional (see section 4.5).

Duration of treatment should be limited to a maximum of 3 days for adults and children aged 1 year and over. The patient should consult a doctor if symptoms persist or worsen.

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

Intestinal absorption of aluminium ions may be enhanced by oral doses of citrates, increasing the toxicity of aluminium.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

There are no or a limited amount of data from the use of glycerol, honey, citric acid monohydrate, lemon oil terpeneless and syrup in pregnant women. As a precautionary measure, it is preferable to avoid the use of the product during pregnancy unless clearly necessary. Consult a healthcare professional before use.

##### **Breast-feeding**

There is insufficient information on the excretion of glycerol, honey, citric acid monohydrate, lemon oil terpeneless and syrup or metabolites in human milk. A risk to newborns/infants cannot be excluded. Consult a healthcare professional before use.

##### **Fertility**

There is no information on the effects of glycerol, honey, citric acid monohydrate, lemon oil terpeneless and syrup on fertility.

#### **4.7 Effects on ability to drive and use machines**

None known.

#### **4.8 Undesirable effects**

Adverse events which have been associated with glycerol, honey, citric acid monohydrate, lemon oil terpeneless and syrup are given below, tabulated by system organ class and frequency.

Frequencies are defined as:

Very common ( $\geq 1/10$ );

Common ( $\geq 1/100$  and  $< 1/10$ );

Uncommon ( $\geq 1/1000$  and  $< 1/100$ );

Rare ( $\geq 1/10,000$  and  $< 1/1000$ );

Very rare ( $< 1/10,000$ );

Not known (cannot be estimated from the available data).

Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
Immune system disorders	Not known	Hypersensitivity

## **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: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

### **4.9 Overdose**

In the unlikely event of overdose, serious side effects are not expected.

If overdose does occur, consult a healthcare professional. Treatment consists of general supportive therapy and may include gastric lavage.

When taken orally large doses of glycerol may cause headache, nausea, and vomiting. Diarrhoea, thirst, dizziness, and mental confusion may occur less frequently. Cardiac arrhythmias have been reported.

Citric acid ingested frequently or in large quantities may cause erosion of the teeth and have a local irritant action or cause diarrhoea.

Overconsumption of sucrose is associated with the formation of dental caries.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Respiratory System; Cough and Cold Preparations; Other Cold Preparations ATC Code: R05X

Glycerol, honey and syrup act as demulcents and provide a soothing medium for an irritated throat.

The citric acid monohydrate and the lemon oil terpeneless both add to the sharpness of the product and enhance the flavour.

### **5.2 Pharmacokinetic properties**

Glycerol is readily absorbed from the gastrointestinal tract and undergoes extensive metabolism, mainly in the liver; it may be used in the synthesis of lipids, metabolised to glucose or glycogen, or oxidised to carbon dioxide and water. It is also excreted in the urine unchanged.

Sucrose is hydrolysed in the small intestine by the enzyme sucrase to glucose and fructose, which are then absorbed.

No relevant pharmacokinetic data are available for citric acid monohydrate, honey or lemon oil terpeneless.

### **5.3 Preclinical safety data**

No preclinical findings of relevance have been reported.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ethanol (96%),  
Nipasept sodium,  
Benzyl Alcohol\* (\*trace amounts present in Lemon Oil Terpeneless),  
Parahydroxybenzoates and their esters\* (\*nipasept sodium contains sodium ethyl p-hydroxybenzoate (E215), sodium propyl p-hydroxybenzoate and sodium methyl p-hydroxybenzoate (E219)),  
Water.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Glass bottle - Three years.  
Transparent blue plastic PETE bottle - Two years.  
Transparent green plastic PETE bottle - Two years.

### **6.4 Special precautions for storage**

Store below 25°C.

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

Amber glass bottles with a polypropylene cap with a polyethylene tamper-evident band with expanded polyethylene wad (100ml and 200ml).  
Transparent blue plastic PETE bottle (180ml).  
Transparent green plastic PETE bottle (180ml).  
Translucent yellow graduated polypropylene measuring cup.  
Pack sizes: 100ml, 180ml and 200ml.  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

Oral administration.

## **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) Limited  
Dansom Lane

Hull  
HU8 7DS

**8    MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0038

**9    DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

24/04/1995

**10    DATE OF REVISION OF THE TEXT**

26/03/2025