

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Dry Cough 0.25ml/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml oral solution contains 0.25 ml Glycerol.

Excipients with known effects:

Sodium 0.83 mg / 5 ml dose. Maximum daily dose (MDD) = 6.64 mg

Ethanol 0.05 ml / 5 ml dose (0.04 mg / 5 ml dose)

Sucrose 3.3 g / 5 ml dose. Maximum daily dose (MDD) = 26.48 g

Invert sugar 500 mg / 5 ml dose. Maximum daily dose (MDD) = 4 g

Benzyl Alcohol (trace amounts present in Lemon Oil Terpeneless)

Parahydroxybenzoates and their esters (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 solution

Clear yellow solution, with characteristic lemon odour.

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

Posology:

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.

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

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

Children aged less than 1 year: Not suitable (see section 4.3)

No special dose is required for elderly patients.

Method of administration:

Oral

4.3 Contraindications

Hypersensitivity to the active substances 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

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

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

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

Contains 3.3 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Also contains 500 mg invert sugars per 5ml dose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

Contains parahydroxybenzoates (sodium ethyl p-hydroxybenzoate (E215), sodium propyl p-hydroxybenzoate and sodium methyl p-hydroxybenzoate (E219)) which may cause allergic reactions (possibly delayed).

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

4.5 Interaction with other medicinal products and other forms of interactions

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

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, terpeneless lemon oil 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. As with many other medicines, this product should be avoided in the first three months of pregnancy.

Breast-feeding

No significant problems have been reported in breast-fed infants from mothers taking this product. It is preferable to avoid the use of the product during lactation to avoid the use of the product during lactation unless the benefits outweighs any risks. 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, terpeneless lemon oil and syrup on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with glycerol, honey, citric acid, monohydrate, terpeneless lemon oil 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.

System Organ Class	Frequency	Adverse Events
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 HPRC Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Symptoms

In the unlikely event of an overdose, serious side effects are not expected. When taken orally, 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.

Management

Consult a healthcare professional. Treatment consists of general supportive therapy and may include gastric lavage.

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 acts as a demulcent and provides a soothing medium for an irritated throat.

Citric acid monohydrate and the lemon oil terpeneless 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 sucrose to glucose and fructose, which are then absorbed.

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

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Honey

Syrup

Citric acid monohydrate

Terpeneless lemon oil (benzyl alcohol)

Ethanol (96%)

Sodium parabens mixture (sodium ethyl p-hydroxybenzoate (E215), sodium propyl p-hydroxybenzoate and sodium methyl p-hydroxybenzoate (E219))

Water, purified.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 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.
Pack size: 100ml, 150ml and 200ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th April 2006

Date of last renewal: 7th April 2011

10 DATE OF REVISION OF THE TEXT

January 2022