Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Chesty Cough 50mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml oral solution contains 50 mg Guaifenesin

Excipients with known effects:
Sodium 1.352 mg (0.06 mmol)/5 ml. Maximum daily dose (MDD)=21.632 mg
Sucrose 3.965 g / 5 ml. Maximum daily dose (MDD) = 63.44 g
Sodium benzoate (E211) 8.452 mg / 5 ml
Benzyl alcohol (trace amounts present in Lemon Oil Terpeneless)

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
Pale yellow or colourless solution, with characteristic lemon odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An expectorant for the symptomatic relief of deep chesty coughs.
Lemsip Chesty Cough 50mg/5ml Oral Solution is indicated in adults and children over 12 years of age.

4.2 Posology and method of administration

Duration of treatment should be limited to a maximum of 5 days. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 5 days

Posology
Adults and children over 12: Two to four 5ml spoonfuls. Dose may be repeated every 4-6 hours up to a maximum of 4 doses in any 24 hour period.

Paediatric population:
When simple measures have failed to provide adequate relief.
Contraindicated for children under 12 years (see section 4.3).

Elderly Population:
No dosage adjustment is considered necessary in the elderly.

Method of administration
For oral administration.
Do not exceed the stated dose. Do not take with any other cough and cold medicine.

4.3 Contraindications

Contraindicated in children under 12 years of age.
Hypersensitivity to guaifenesin or to any of the excipients listed in section 6.1.
Do not take if suffering from porphyria.

4.4 Special warnings and precautions for use

Do not exceed the stated dose. Do not take with any other cough and cold medicine.

Seek medical advice if suffering from chronic cough or asthma.

Use with caution in patients with renal impairment.

Not recommended for concomitant use with a cough suppressant.

Do not take if you are pregnant or breast feeding unless recommended by a health care professional (see section 4.6).

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

Contains 3.965 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Also contains 8.452 mg of sodium benzoate and 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

If urine is collected within 24 hours of a dose of the medicinal product, a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Guaifenesin may increase the rate of absorption of paracetamol.

Paediatric population
Interaction studies have only been performed in adults

4.6 Fertility, pregnancy and lactation

Pregnancy:
The product should not be used during pregnancy unless recommended by a healthcare professional.
There are limited data on the use of guaifenesin in pregnant women.

Breastfeeding:
The product should be avoided during lactation unless recommended by a healthcare professional.
There is insufficient information on the excretion of guaifenesin /metabolites in human milk.

Fertility:
No known effects.

4.7 Effects on ability to drive and use machines

The 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 guaifenesin are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥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.

The list of the following adverse effects relates to those experienced with guaifenesin at OTC doses (maximum 800mg per day), in shortterm use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Gastrointestinal Disorders	Not known	Abdominal discomfort, nausea, vomiting

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
Overdose with guaifenesin is unlikely to produce toxic effects since its toxicity is low.

Symptoms associated with guaifenesin overdose include headache, dizziness, nausea and vomiting. Extremely high doses may depress the central nervous system and act as a muscle relaxant. Prolonged use of guaifenesin may result in urolithiasis. The drug is, however, rapidly metabolised and excreted in the urine.

Management
Patients should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Respiratory system,Cough and cold preparations, Expectorants
ATC Code: R05CA03

Guaifenesin is an expectorant which increases the volume of mucous that can be expelled or cleared by mucocilliary action due to reduction in the adhesiveness and viscosity of tenacious sputum.

The active ingredients are not known to cause sedation.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract after oral administration and rapidly metabolised by oxidation to β-(2-methoxyphenoxy)-lactic acid. Approximately 40% of a dose is excreted as this metabolite in the urine within three hours. The half-life in plasma is approximately one hour.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose (extra fine sugar)
Glycerol
Tolu flavour solution
Sodium benzoate
Citric acid anhydrous granular
Sodium citrate
Lemon oil terpeneless
Isopropanol
Sodium cyclamate
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

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, 200ml, 300ml.

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

PA0979/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 7 April 2006

Last Date of Renewal: 7 April 2011

10 DATE OF REVISION OF THE TEXT

February 2021