SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Adult Meltus Chesty Coughs Sugar & Colour Free
Lemsip Cough for Mucus Cough & Catarrh 100mg/2.5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Adult Meltus Chesty Coughs Sugar & Colour Free contains per 5 ml dose:
Guaiphenesin 100 mg
Cetylpyridinium chloride 2.5 mg

Excipient(s) with known effect:

- Sodium
- Liquid Sorbitol (E420)
- Glycerol
- Ethanol

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

Clear, pale straw coloured liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of *acute chesty* coughs and catarrh associated with influenza, colds and mild throat infections.

4.2 Posology and method of administration

Glass bottle - Adults and children 12 years and over:

One or two 5 ml spoonfuls to be taken and swallowed slowly every four to six hours.

PETE plastic bottle - Adults and children 12 years and over:

5 ml (fill the measure cup to 5 ml) or 10 ml (fill measure cup to 10 ml) every 4 – 6 hours. To be taken every 4 – 6 hours up to a maximum of 4 doses in any 24-hour period. Rinse the measure cup after use.

Children aged 6 to 12 years: Not recommended.

Children under 6 years: This product is contraindicated in children under 6 years of age.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Ask your doctor before use if you suffer from a chronic cough, if you have asthma or are suffering from an acute asthma attack.

Stop use and ask a healthcare professional if your cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash, or persistent headache.

Do not take with a cough suppressant.

Use with caution in patients suffering from porphyria.

Not suitable for children under 12 years of age.

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

This medicinal product contains 9.0% v/v of ethanol, i.e., this medicine contains 0.38 mg of alcohol (ethanol) in each 5ml dose, the amount in a 5ml dose of this medicine is equivalent to less than 1ml of beer or 1ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 2.5mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor has told you that you 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 take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

Can cause transient abnormality in platelet aggregation patterns determined one hour after ingestion.

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).

4.6 Fertility, Pregnancy and lactation

No known contraindications.
There is limited amount of data from the use of Guaifenesin in pregnant women.

There is no information on use in lactation.

Therefore, it should not be used during pregnancy or breastfeeding unless advised by a doctor or a pharmacist.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse events which have been associated with guaifenesin and cetylpyridinium chloride 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.

System Organ Class	Frequency	Adverse Events
Immune system disorders	Not known	Hypersensitivity reactions
Gastrointestinal disorders	Not known	Abdominal discomfort, nausea, vomiting and diarrhoea.

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

4.9 Overdose

Very large doses may cause nausea and vomiting. Prolonged use of guaifenesin may result in urolithiasis. It is however, rapidly metabolised and excreted in the urine. The patient should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cough and cold preparations, Expectorants**;**
ATC Code: R05CA10

A cough linctus containing an expectorant and an oral antiseptic in a sugar and colour free base. The expectorant, guaifenesin, is employed to produce a thinning of mucous secretions increasing the volume of mucus that can be expelled by mucociliary action due to a reduction in the adhesiveness and viscosity of tenacious sputum. Thus providing relief to bronchial catarrh.

The antiseptic, cetylpyridinium chloride, is used for the treatment of superficial mouth infections and has an antibacterial activity on Gram-positive bacteria.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract after oral administration and rapidly metabolised by oxidation to beta-(2-methoxyphenoxy)-lactic acid. Within 3 hours, approximately 40% of a single dose is excreted in the urine as this metabolite. The half-life in plasma is approximately 1 hour.

Guaifenesin may increase the absorption rate of paracetamol, however the clinical relevance of this is unknown.

No pharmacokinetic data are available for cetylpyridinium chloride.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Ethanol 96%
Levomenthol
Liquid Sorbitol Non-Crystallising (E420)
Saccharin Sodium
Sodium Cyclamate
Povidone
Custard Flavour
Raspberry Flavour
Blackberry Flavour
Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

Glass bottle - Five years unopened.
Transparent blue plastic PETE bottle – Two years unopened.
Transparent green plastic PETE bottle – Two years unopened.

6.4 Special precautions for storage

Do not store above 25ºC.

Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass sirop bottle fitted with tamper evident polypropylene cap with expanded polyethylene liner, packed in printed cartons containing 100ml of linctus.

Transparent blue plastic PETE bottle (180 ml).

Transparent green plastic PETE bottle (180 ml)

Translucent yellow graduated polypropylene measuring cup.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited
103-105 Bath Road,
Slough,
Berkshire,
SL1 3UH,
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0760

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/10/1995 / 14/09/2001

10 DATE OF REVISION OF THE TEXT

23/05/2025