# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Robitussin Chesty Cough 100mg/5ml Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 100 mg Guaifenesin.

Excipients with known effect
Ethanol (96%): 114.9 mg
Liquid Maltitol (Lycasin 80/55) (E965): 242 mg
Propylene glycol (E1520): 7.59 mg
Sodium benzoate (E211): 6.0 mg
Sodium: 11.9 mg
Liquid Sorbitol Non-Crystallising (E420): 1338 mg

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral solution
A deep russet coloured syrupy liquid with a characteristic odour and flavour of cherry.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Expectorant used as an adjunct in the treatment of productive cough.

### 4.2 Posology and method of administration

**Adults and children over 12 years:** The usual daily dose is 10ml four times daily
**Children** under 12 years**:** Do not use

### 4.3 Contraindications

Use in children under 12 years of age.
Hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings and precautions for use

Caution should be exercised in patients with chronic cough as occurs with smoking or chronic lung disease such as asthma or emphysema.

A doctor or healthcare professional should be sought if cough lasts more than 5 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose.

This product should not be taken with any other cough and cold medicine.

Excipient warnings:

- This medicine contains 230 mg of alcohol (ethanol 96%) in each 10 ml dose which is equivalent to 23 mg/ml (2.30% w/v). The amount in 10 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

- Patients with rare hereditary problems of fructose intolerance should not take this medicine because this product contains liquid sorbitol non-crystallising and maltitol.
- This medicine contains 2675 mg liquid sorbitol non-crystallising per 10 ml dose which is equivalent to 267.5 mg/ml. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 12.0 mg sodium benzoate in each 10 ml dose which is equivalent to 1.2 mg/ml.
- This medicine contains 15.2 mg propylene glycol in each 10 ml which is equivalent to 1.5 mg/ml.
- This medicinal product contains 23.9 mg sodium per 10 ml, equivalent to 1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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

None stated.

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**
The safety of guaifenesin when used during pregnancy has not been established. Medical advice should be sought before using guaifenesin during pregnancy and it should not be used unless the potential benefit to the mother clearly outweighs the possible risk to the developing foetus.

**Lactation**
No relevant data are available. It is not known whether guaifenesin passes into breast milk. Guaifenesin should not be used while breast-feeding without medical advice.

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

None stated.

**4.8 Undesirable effects**

Adverse reactions identified during post-marketing use are listed below by MedDRA System Organ Class. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be rare or very rare.

| | |
|---|---|
| *Immune system disorders* | *Very rare or rare:* hypersensitivity, anaphylactic reactions and angioedema. |
| *Respiratory, thoracic and mediastinal disorders* | *Dyspnoea** |
| *Gastrointestinal disorders* | *Very rare or rare:* nausea, vomiting, abdominal discomfort. |
| *Skin and subcutaneous tissue disorders* | Urticaria, rash. |

*Dyspnoea has been reported in association with other symptoms of 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 HPRA Pharmacovigilance,. Website: www.hpra.ie;

**4.9 Overdose**

**Symptoms**
The following signs and symptoms may be associated with an overdose of Guaifenesin:

*Gastrointestinal disorders*
Nausea, vomiting.

**Management**
In case of accidentally overdose, discontinue use and seek professional assistance immediately. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated. Further management should be as clinically indicated or as recommended by the national poison centres where available.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Guaifenesin is a proven expectorant which loosens mucous in the chest and make it easier to bring out.

### 5.2 Pharmacokinetic properties

Guaifenesin is absorbed from the GI tract. It undergoes metabolism and is excreted in the urine.

### 5.3 Preclinical safety data

Non-clinical safety data on guaifenesin have not revealed findings which are of relevance to the recommended dosage and use of the product.

There are no experimental data available for guaifenesin from repeated dosing studies carried out over longer periods of time or from mutagenicity, carcinogenicity or relevant reproductive toxicity studies.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carmellose sodium
Sodium Benzoate (E211)
Ethanol (96%)
Levomenthol
Citric Acid Anhydrous
Liquid Maltitol (Lycasin 80/55) (E965)
Caramel (E150d)
Natural Cherry Flavour*
Liquid Sorbitol Non-Crystallising (E420)
Sodium Cyclamate
Acesulfame Potassium Salt
Purified Water

* contains: ethanol (96%), propylene glycol and natural flavourings
** does not contain sucrose

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

27 months.

### 6.4 Special precautions for storage

Do not store above 25$^{o}$C.

### 6.5 Nature and contents of container

Brown glass bottle, hydrolytic class 3, containing 100 ml or 200ml with child resistant caps.

A transparent polypropylene measuring cap is also included.

### 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

Haleon Ireland Limited,
Clocherane, Youghal Road,
Dungarvan,
Co. Waterford, X35 Y983,
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA0678/153/001

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

Date of first authorisation: 1st April 1983
Date of last renewal: 1st April 2008

**10 DATE OF REVISION OF THE TEXT**

July 2025