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 wine-russet coloured oral solution with a raspberry odour and taste.

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 interactions

None stated.

4.6 Fertility, pregnancy and lactation

Consult a doctor before use.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Immune system disorders	Hypersensitivity
Gastrointestinal disorders	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, Website: www.hpra.ie;

4.9 Overdose

In case of accidental overdose, discontinue use and seek professional assistance immediately.

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

Nervous system disorders:
Dizziness

Skin and subcutaneous tissue disorders:
Rash

Gastrointestinal disorders
Nausea, vomiting

Treatment is by gastric lavage together with appropriate supportive therapy dependent upon individual response to the various constituents of the preparation.

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

None stated.

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

PET bottles containing 100ml or 250ml with PET-lined PP/HDPE child resistant screw caps.

A clear polypropylene measuring cup 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

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/153/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

February 2021