SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Robitussin Chesty Cough Junior 50 mg / 5 ml Oral Solution /
Robitussin Chesty Cough Kids 50 mg / 5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Guaifenesin 50mg
For excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Expectorant for the symptomatic relief of acute productive (chesty) cough.

The oral solution is for the lubrication and relief of the sore throat and hoarseness, which may be associated with the cough.

4.2 Posology and method of administration

The following dose is taken 4 hourly. Do not exceed 6 doses in 24 hours.

This medicine is contra-indicated in children under 6 years of age.

6 – 10 years 5 to 10ml

Not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical advice if the child's condition deteriorates during treatment.

Do not exceed the stated dose

Keep out of the sight and reach of children.

4.3 Contraindications

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

Not to be used in children under 6 years of age.

4.4 Special warnings and precautions for use

Consult a doctor before use if suffering from an acute asthma attack, a chronic cough or are asthmatic.
Stop use and consult a healthcare professional if the cough persists for longer than 5 days.
Stop use and consult a healthcare professional if the cough is accompanied by a fever, rash or persistent headache or is recurrent.
If symptoms persist, consult a doctor.
Keep out of the sight and reach of children.
Do not exceed the stated dose.
Do not take with any other cough and cold medicine, including cough suppressants.

4.5 Interaction with other medicinal products and other forms of interaction

Should not be taken with a cough suppressant.

If urine is collected within 24 hours of a dose of this medicine 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 special warnings or precautions.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following side effects may be associated with the use of guaifenesin:
Gastro-intestinal Disorders: nausea, vomiting
Immune System Disorders: hypersensitivity reactions

4.9 Overdose

Symptoms of very large overdosage are nausea and vomiting. Guaifenesin is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract. It is readily metabolised and excreted in the urine. It has a plasma half life of 1 hour.

5.3 Preclinical safety data
None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium benzoate
Sodium Saccharin
Glycerol
Sorbital solution (70%) (Non-cryst)
Citric acid monohydrate or anhydrous citric acid
Blackcurrant flavour DA13624
Vanilla flavour NN21166
Acesulfame Potassium
Hydroxyethylcellulose
Purified water

6.2 Incompatibilities
None.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 25º C.

6.5 Nature and contents of container
Container: Amber glass bottles
Closure: Wadded, aluminium roll-on pilfer-proof closure (ROPP)
or
Wadded, polypropylene or polypropylene/HDPE child resistant tamper evident closure
Wad: PVdC-coated. Board or EPE

Each bottle contains 100 ml or 150ml

6.6 Special precautions for disposal and other handling
Keep all medicines out of the reach of children.

7 MARKETING AUTHORISATION HOLDER
Haleon UK Trading Limited
The Heights
Weybridge
Surrey

KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0174

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/01/2005

10 DATE OF REVISION OF THE TEXT

20/03/2024