SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Robitussin Chesty Cough with Congestion

Robitussin Mucus Cough and Congestion Relief 20mg, 6mg/ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Guaifenesin, 100mg per 5ml
Pseudoephedrine Hydrochloride, 30mg per 5ml

Excipients with known effect
Amaranth (E123): 0.066 mg of Amaranth in each 10 ml dose
Ethanol: 242 mg of alcohol (ethanol) in each 10 ml dose
Maltitol (E965): 484 mg of maltitol in each 10 ml dose
Propylene glycol (E1520): 15.2 mg propylene glycol in each 10 ml dose
Sodium benzoate (E211): 12.0 mg of sodium benzoate in each 10 ml dose
Sodium: 27.5mg sodium in each 10 ml dose
Sorbitol (E420): 2094 g sorbitol in each 10 ml dose

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Pale pink clear liquid for oral administration

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nasal decongestant and expectorant for the symptomatic relief of respiratory tract disorders.

4.2 Posology and method of administration

Oral Administration.
Adults, (including the elderly) and children aged 12 years and over: One 10ml measure every 4-6 hours up to four times daily.
Children under 12 years: Do not use.

Do not exceed the stated dose.
Do not use with other nasal decongestants or expectorants.
Minimum dosing interval: 4 hours.
Maximum duration of use without medical advice: 7 days.
Maximum daily dose: 40 ml in any 24 hours (pseudoephedrine hydrochloride 240 mg, guaifenesin 800 mg).

4.3 Contraindications

Prior hypersensitivity reaction to pseudoephedrine, guaifenesin or any of the excipients.
Cardiovascular disease including hypertension, ischaemic heart disease, thyrotoxicosis, glaucoma, diabetes, enlargement of the prostate or urinary retention.
Do not use in patients with severe renal impairment.
Concomitant use of other sympathomimetic decongestants.
Patients taking a prescription monoamine oxidase inhibitor (MAOI) or for 14 days after stopping the MAOI drug. (See section 4.5).
Patients who are taking the oxazolidinone class of antibiotics (such as linezolid) or beta-blockers (see Section 4.5).
Patients with phaeochromocytoma.
Use in children under 12 years of age.
Patients with severe hypertension or uncontrolled hypertension.
Patients with severe acute or chronic kidney disease/renal failure.

4.4 Special warnings and precautions for use

Caution should be exercised in patients with arrhythmias and hyperthyroidism.

Pseudoephedrine should be used with caution in those with moderate to severe renal impairment.

Special care is advisable in patients receiving antihypertensive therapy or tricyclic antidepressants (See section 4.5).

Acute systemic vasoconstrictive events may occur:

- Acute Coronary Syndrome (ACS): Symptoms include sudden chest pain, tightness, heavy sweating and dyspnoea at rest.
- There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued immediately, and medical advice sought if any signs/symptoms or PRES/RCVS develop.

Use with caution in patients taking vasoconstrictor agents such as ergot alkaloids (ergotamine and methsergide): increased risk of ergotism (See Section 4.5).

Patients suffering from a chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema may require additional investigation and should seek medical advice to exclude underlying pathology.

Additional investigation may be required if symptoms of cough, nasal and sinus congestion do not improve within 7 days, worsen, or are accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition. This product should not be taken with a cough suppressant.

Acute perioperative hypertension may occur if volatile halogenated anaesthetics are used simultaneously with indirect sympathomimetic. When planning surgery, it is recommended that pseudoephedrine treatment is stopped several days before anaesthesia.

Pseudoephedrine contains an active substance that may result in a positive reaction during antidoping control tests.

Use in caution in patients with occlusive vascular disease.

Keep out of sight and reach of children.

Severe Skin reactions
Severe skin reaction such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of Robitussin Chesty Cough with Congestion / Robitussin Mucus Cough and Congestion Relief should be discontinued and appropriate measures taken if needed.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).
Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache,

nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Stop use and ask your healthcare professional if your cough lasts more than 7 days, comes back or is accompanied by a fever, rash or persistent headache.

Do not exceed recommended dose.

Excipient warnings:

- Patients with rare hereditary problems of fructose intolerance should not take this medicine because this product contains Sorbitol and Maltitol.
- This medicinal product contains 27.5 mg sodium per 10 ml, equivalent to 1.4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- This product contains Amaranth (E123), which may cause allergic reactions.
- This medicine contains 242 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 24 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. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women and high-risk groups such as patients with liver disease, or epilepsy.
- 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 medicine contains 2094 mg sorbitol per 10 ml dose which is equivalent to 209.4 mg/ml. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

Not to be used in patients taking monoamine inhibitors or within 14 days of stopping treatment as there is a risk of hypertensive crisis when MOAI are taken in combination with sympathomimetics.

Concomitant use of pseudoephedrine-containing products with other sympathomimetic agents such as decongestants or tricyclic antidepressants may occasionally cause a rise in blood pressure. An increased risk of cardiac arrhythmias may occur if sympathomimetics are given to patients receiving cardiac glycosides.

The oxazolidinone class of antibiotics (such as linezolid) are known to cause a dose-related inhibition of monoamine oxidase. Therefore, they should not be taken together as there is a potential to cause hypertensive crisis (see Section 4.3).

Pseudoephedrine may interact with:

- halogenated anaesthetics (see Section 4.4)
- moclobemide: risk of antihypertensive crisis
- appetite suppressants and amphetamine-like psychostimulants: risk of hypertension

Pseudoephedrine may enhance the effects of anticholinergic drugs (such as TCAs).

Vasoconstrictor agents, including ergot derivatives (such as ergotamine, dihydroergotamine and methysergide). Concomitant administration may cause an increased risk of ergotism (see Section 4.4).

Alcohol
A dose of 10ml of this medicine administered to an adult weighing 70 kg would result in exposure to 3.0 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.5 mg/100 ml.

A dose of 10ml of this medicine administered to a child over 12 years of age and weighing 40 kg would result in exposure to 5.42 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.9 mg/100 ml

For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml. Co-administration with medicines containing e.g.propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

4.6 Fertility, pregnancy and lactation

If pregnant or breastfeeding, consult a healthcare professional before use.

Pregnancy

Guaifenesin:

Although adequate and well-controlled studies in pregnant women have not been done, the Collaborative Perinatal Project monitored 197 mother-child pairs exposed to guaifenesin during the first trimester. An increased occurrence of inguinal hernias was found in the neonates. However, congenital defects were not strongly associated with guaifenesin use during pregnancy in 2 large groups of mother-child pairs.

Pseudoephedrine:

Data on pregnancy outcomes after maternal exposure to pseudoephedrine are limited. Two analyses of health maintenance organisation pharmacy data identified 9 malformed infants among 902 first-trimester pseudoephedrine exposures suggesting no specific association with birth defects overall. However the related compounds epinephrine, ephedrine and phenylephrine have been associated with haemorrhages and cardiovascular and limb malformations in animal models. The vasoconstrictive effects of these drugs may indicate that their use in early pregnancy might increase the risk of vascular disruption defects.

Breastfeeding:

Guaifenesin and pseudoephedrine are excreted in breast milk in small quantities. It is estimated that 0.5% to 0.7% of a single dose of pseudoephedrine ingested by the mother will be excreted in breast milk over 24 hours.

Caution should therefore be exercised by balancing the potential benefit of treatment against any possible risks.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by dizziness.

4.8 Undesirable effects

Pseudoephedrine
The following adverse reactions have been reported with pseudoephedrine:

System Organ Class	Adverse Reaction	Frequency
Psychiatric Disorders	Nervousness, insomnia	Common
	Agitation, restlessness	Uncommon
	Hallucinations (particularly in children)	Rare
	Anxiety, irritability, excitability	Not known
Nervous System Disorders	Dizziness	Common
	Headache, tremor	Not known
	Posterior reversible encephalopathy syndromes (PRES) (see Section 4.4)	Not known
	Reversible cerebral vasoconstriction syndrome (RCVS) (see Section 4.4)	Not known
Cardiac Disorders	Tachycardia, palpitations	Rare
Vascular Disorders	Increased blood pressure[1]	Rare
Immune System Disorders	Hypersensitivity	Not known
Gastrointestinal Disorders	Vomiting, dry mouth, nausea	Common
	Ischaemic colitis	Not known
Skin and Subcutaneous Tissue Disorders	Acute generalised exanthematous pustulosis (AGEP), allergic dermatitis[2], rash	Rare
Renal and Urinary Disorders	Dysuria, urinary retention[3]	Uncommon
Eye Disorders	Ischaemic optic neuropathy	Not known

[1]*Increases in systolic blood pressure have been observed. At therapeutic doses, the effects of pseudoephedrine on blood pressure are not clinically significant.*

[2]*A variety of allergic skin reactions, with or without systemic features such as bronchospasm and angioedema have been reported following use of pseudoephedrine.*

[3]*Urinary retention is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.*

Guaifenesin

Post-Marketing Data

System Organ Class	**Adverse Reaction**	**Frequency**
Immune System Disorders	Anaphylactic reactions, angioedema, hypersensitivity reactions	Rare
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea[4]	Rare
Gastrointestinal Disorders	Vomiting, nausea, abdominal discomfort	Rare
Skin and subcutaneous Disorders	Urticaria, rash	Rare

[4]***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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

Symptoms:
Guaifenesin overdose: Nausea and vomiting.

Pseudoephedrine overdose: Bradycardia, palpitation, tachycardia, nausea, vomiting, convulsion (seizure), dizziness, tremor, agitation, anxiety, insomnia, irritability, nervousness, restlessness, hypertension, increased blood pressure, psychosis and hallucinations. Serum potassium levels may be low due to extracellular to intracellular shifts in potassium.

Treatment: Appropriate supportive therapy dependent upon individual response to the preparation. Beta blockers should reverse the cardiovascular complications and the hypokalaemia. Vomiting would be treated by fluid replacement and monitoring of electrolytes.

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
Pharmacotherapeutic group: Expectorant
ATC code: RO5CAO3

Guaifenesin has an expectorant action which increases the output of respiratory tract fluid by reducing adhesiveness and surface tension. The increased flow of less viscid secretion promotes ciliary action and facilitates the removal of mucus. This changes a dry unproductive cough to a cough that is more productive and less frequent.

Pseudoephedrine Hydrochloride
Pharmacotherapeutic group: Sympathomimetic
ATC code: R01BA02

Pseudoephedrine is a stereoisomer of ephedrine and has a similar action, but has been stated to have less pressor activity and central nervous system effects.

It is a sympathomimetic agent with indirect and direct effects on adrenergic receptors and is an orally effective upper respiratory tract decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation in systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.

5.2 Pharmacokinetic properties

Guaifenesin

Guaifenesin is well absorbed from the gastro intestinal tract following oral administration. Guaifenesin has a plasma half-life of approximately 1 hour. It is rapidly hydrolyzed (60% within seven hours) and then excreted in the urine, with beta-(2-methoxyphenoxy)-lactic acid as its major urinary metabolite.

Pseudoephedrine

Pseudoephedrine is absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged (55-75%) in the urine together with small amounts of its hepatic metabolite. It has a half-life of several hours; elimination is enhanced and half-life accordingly shorter in acid urine.

Pseudoephedrine is primarily excreted by the kidneys. Renal impairment will result in increased plasma levels.

5.3 Preclinical safety data

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

Although no carcinogenicity data are available for pseudoephedrine hydrochloride, this compound did not induce mutations at the tk locus of mouse lymphoma cells in the absence or presence of a metabolic activation system and it did not induce micronuclei in polychromatic erythrocytes of bone marrow in mice.

When orally administered to rats during organogenesis, pseudoephedrine caused severe maternal toxicity following administration of a dose that was 8-fold greater than clinical dose, while doses that were equivalent to or 2.7-fold greater than clinical dose resulted in slight maternal toxicity. However, there were no adverse developmental effects following oral administration of a dose that was equivalent to the clinical dose. No maternal or developmental toxicity was observed when a dose that was 1.3-fold greater than clinical dose was orally administered to rabbits on day 6 through 18 of gestation.

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

Glycerol, Sodium Carboxymethyl Cellulose, Disodium Edetate, Sodium Benzoate, Sodium Cyclamate, Amaranth (E123), Ethanol, Levomenthol, Maltitol, Sorbitol Solution 70%, Natural Cherry Flavouring, Citric Acid Anhydrous, Caramel E150, Acesulfame Potassium and Purified Water.

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25□C.

6.5 Nature and contents of container

PET bottles containing 100ml with PET lined PP/HDPE screw caps.

A clear polypropylene measuring cap also included.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0208

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/09/1993

10 DATE OF REVISION OF THE TEXT

07/06/2024