AUSTRALIAN PRODUCT INFORMATION – Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid® (Guaifenesin, Pseudoephedrine hydrochloride)

1. NAME OF THE MEDICINE

Guaifenesin, Pseudoephedrine hydrochloride.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL of Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid contains Guaifenesin 200 mg and Pseudoephedrine hydrochloride 60 mg.

Excipients with known effects:
- Ethanol
- Saccharin Sodium
- Sodium Benzoate
- Sorbitol

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Oral liquid.

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid is a clear, red coloured syrup with a cherry odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief from symptoms of chesty cough and cold; helps loosen phlegm and thin bronchial secretions to make coughs more productive (expectorant) and provides symptomatic relief from nasal, chest and sinus congestion due to common cold.

4.2 Dose and method of administration

Dosage
Every 4 to 6 hours orally when necessary.

Adults and children 12 years and over: 10 mL
Children 6 years to under 12 years: 5 mL

Do not exceed 4 doses in 24 hours.

Do not use in children under 6 years of age. Use in children aged 6-11 years only on the advice of a doctor, pharmacist or nurse practitioner.

Do not use in children under 6 years.

4.3 Contraindications

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to guaifenesin, pseudoephedrine or any of the other ingredients in the product.
- with severe hypertension or coronary artery disease;
- taking monoamine oxidase inhibitors (MAOIs) or who have been taking the MAOI within the last 14 days
- under 6 years of age

4.4 Special warnings and precautions for use

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid should be used with caution in patients with:

- hypertension
- hyperthyroidism
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy
- severe hepatic or renal dysfunction.
- porphyria, as guaifenesin is possibly porphyrogenic.

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid should not be used in patients with chronic or persistent cough associated with chronic lower respiratory tract diseases such as asthma, bronchitis, chronic obstructive pulmonary disease (COPD), emphysema or smoker's cough or cough associate with excessive secretions.

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid should not be taken for longer than a few days.

Pseudoephedrine may cause sleeplessness if it is taken up to several hours before going to bed.

Patients should not exceed the recommended dosage.

This product should be kept out of reach of children.

Refer to Section 4.5 Interactions with other medicines and other forms of interactions for additional information.

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.

Use in hepatic impairment
This product should be used in caution in patients with impaired hepatic function.

Use in renal impairment
This product should be used in caution in patients with impaired renal function.

Use in the elderly
Refer to section 4.8 Adverse effects.

Paediatric use
Refer to section 4.8 Adverse effects.

Effects on laboratory tests
No data available.

4.5 Interactions with other medicines and other forms of interactions

There are no reported interactions with other medicines and guaifenesin.

The following interactions with pseudoephedrine have been noted:

- Antidepressant medication e.g., tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis (refer to Section 4.3 Contraindications for further information)
- other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects
- Antihypertensive medication e.g., methyldopa and β-blockers – may cause an increase in blood pressure
- urinary acidifiers enhance elimination of pseudoephedrine
- urinary alkalinisers decrease elimination of pseudoephedrine

4.6 Fertility, pregnancy and lactation

Effects on fertility
No data available.

Use in pregnancy – Pregnancy Category B2
Drugs which have been taken by only a limited number of pregnant women or women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals are inadequate, or may be lacking, but available data show no

evidence of an increased occurrence of fetal damage.

Safety in pregnancy has not been established, therefore Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid should not be used in pregnant women, or those likely to become pregnant, unless the expected benefit outweighs any potential risk.

Use in lactation
It is not known whether guaifenesin is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant. Small amounts of pseudoephedrine are excreted in breast milk, but the effect on breastfed infants is unknown. Therefore it is not recommended for breastfeeding mothers unless the expected benefits outweigh any potential risk.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (undesirable effects)

The following adverse reactions may be associated with the use of Guaifenesin/pseudoephedrine containing products:

- **Cardiac disorders:** palpitation, tachycardia or arrhythmias
- **Gastrointestinal disorders:** nausea, vomiting, diarrhoea, stomach pain, ischaemic colitis (frequency unknown)
- **Immune system disorders:** hypersensitivity reactions
- **Nervous system disorders:** dizziness, headache, drowsiness, psychomotor hyperactivity
- **Psychiatric disorders:** agitation, anxiety, excitability, insomnia, irritability, nervousness, restlessness, tremors and (rarely) hallucinations
- **Renal and urinary disorders**: urinary retention
- **Skin and subcutaneous tissue disorders:** rash, urticaria.
- **Vascular disorders:** hypertension, increased blood pressure

Children and the elderly are more likely to experience adverse effects than other age groups.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 Overdose

Symptoms which may be associated with high doses (overdosage) of guaifenesin/pseudoephedrine:

Cardiac disorders
Bradycardia, palpitation, tachycardia

Gastrointestinal disorders
Vomiting, nausea, diarrhoea and stomach pain

Nervous system disorders
Convulsion, dizziness, tremor, headache & drowsiness

Psychiatric disorders
Agitation, anxiety, insomnia, irritability, restlessness, nervousness

Skin disorders
Rash

Vascular disorders
Hypertension, increased blood pressure

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action
Guaifenesin is an expectorant, which clears chest congestion by loosening and reducing the viscosity of phlegm, increasing the volume of phlegm and making coughs more productive.

Pseudoephedrine has direct- and indirect- sympathomimetic activity and is an effective decongestant in the upper respiratory tract. It is a stereoisomer of ephedrine and has a similar action, but has been found to have less pressor activity and fewer central nervous system (CNS) effects.

Sympathomimetic agents are used as nasal decongestants to provide symptomatic relief. They act by causing vasoconstriction resulting in redistribution of local blood flow to reduce oedema of the nasal mucosa, thus improving ventilation, drainage and nasal stuffiness.

Clinical trials
No data available.

5.2 Pharmacokinetic properties

Guaifenesin is well absorbed from the gastrointestinal tract. It is metabolised primarily to Beta-2-methoxyphenoxy-lactic acid and then excreted in the urine. In a study where subjects were given 400mg of guaifenesin orally, no unchanged drug could be detected in the urine. The plasma half life of guaifenesin is one hour.

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite. It has a half-life of about 5-8 hours; elimination is enhanced and half-life reduced accordingly in acid urine. Small amounts are distributed into breast milk.

5.3 Preclinical safety data

Genotoxicity
No data available.

Carcinogenicity
No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (3.8% v/v), Cherry Pistachio, Citric Acid, Allura Red AC, Glycerol, Menthol, Propylene Glycol, Raspberry Superarome, Saccharin Sodium, Sodium Benzoate, Sorbitol Solution (70% crystallizing) and Purified Water.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store below 25°C. Do not refrigerate.

6.5 Nature and contents of container

Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid is packed in bottles.

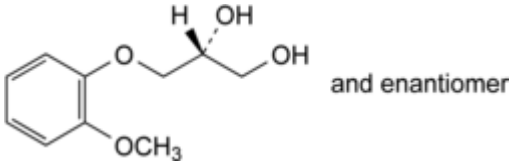
Pack Sizes:
100mL: currently marketed.
25mL: professional sample.

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

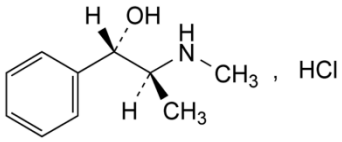
6.7 Physicochemical properties

Chemical structure
Guaifenesin is chemically known as (2RS)-3-(2-Methoxyphenoxy)propane-1,2-diol. It has a molecular formula of $C_{10}H_{14}O_4$ and molecular weight of 198.2. The chemical structure is shown below:



Guaifenesin is a white or almost white, crystalline powder, that is sparingly soluble in water and soluble in alcohol.

Pseudoephedrine hydrochloride is chemically known as (1*S*,2*S*)-2-(Methylamino)-1-phenylpropan-1-ol hydrochloride. It has a molecular formula of $C_{10}H_{16}ClNO$ and molecular weight of 201.7. The chemical structure is shown below:



Pseudoephedrine hydrochloride is a white, crystalline powder or colourless crystals, freely soluble in water and in alcohol, and sparingly soluble in methylene chloride

CAS number
Guaifenesin: 93-14-1
Pseudoephedrine hydrochloride: 345-78-8

7. MEDICINE SCHEDULE (POISONS STANDARD)

Pharmacist Only Medicine (S3).

8. SPONSOR

Pfizer Australia Pty Limited
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Web: www.robitussin.com.au

9. DATE OF FIRST APPROVAL

30 August 1991

10. DATE OF REVISION

23 July 2019

Summary Table of Changes

Section changed	Summary of new information
All sections	New format Update ingredient names to AAN
4.2	Addition of the statement "Do not use in children under 6 years."
4.4, 4.8	Update to include "ischaemic colitis" related safety information
5.2	Deletion of the 'Pharmacology' statement: "Robitussin Chesty Cough & Nasal Congestion PS Oral Liquid combines the expectorant action of guaifenesin with the decongestant action of pseudoephedrine"
6.7	Addition of Physicochemical properties
8	Change in address details