Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Robitussin Plus Oral Solution Guaifenesin 100 mg/5ml Pseudoephedrine HCl 30 mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of liquid contains:

Guaifenesin	100 mg
Pseudoephedrine HCl	30 mg
Excipients with known effect	
Each 5ml contains;	
Ethanol (96%)	114.9 mg
Sodium	13.76 mg
Amaranth (E123)	0.033 mg
Liquid Maltitol (E965)	242 mg
Sorbitol Solution 70% (E420)	1.454 g
Propylene glycol (E1520)	7.59 mg
Sodium benzoate (E211)	6.0 mg

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Solution
A clear, pale pink-coloured liquid with a cherry flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fixed combination of sympathomimetic and expectorant for use as a nasal decongestant and expectorant.

4.2 Posology and method of administration

Posology

Adults (includingelderly) and childrenover12years:

10 ml x 3 daily (this dose is not to be exceeded)

At least 4 hours should elapse between two doses.
This medicine is not to be used with other nasal decongestants or expectorants. The treatment duration should not exceed 5 days without medical advice.

The maximum daily dose is 30 ml in any 24 hours (pseudoephedrine hydrochloride 240 mg, guaifenesin 800 mg).

Paediatric population

This medicine should not be used in children under 12 years.

Elderly
Caution is advised in patients over the age of 60 years. Patients in this age group are at greater risk of adverse reactions due to decreased renal function (see Section 4.4).

Renal Impairment
Do not use in patients with severe renal impairment (GFR <30 ml/min) (see Section 4.3 and 4.4).

Hepatic Impairment
Pseudoephedrine should be used cautiously in patients with severe hepatic impairment.

Method of administration
Take orally.

4.3 Contraindications

This medicine should not be given to children below 12 years of age (see Section 4.2).
Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.
This medicine must not be used to treat patient with severe hypertension, acute ischaemic heart disease, glaucoma, thyrotoxicosis or urinary retention (see Section 4.4).
Patients taking a prescription monoamine oxidase inhibitor (MAOI) or for 14 days after stopping the MAOI drug (see Section 4.5).
Patients receiving other sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like medicines) or tricyclic antidepressants (see Section 4.4).
Patients who are taking the oxazolidinone class of antibiotics (including linezolid) (see Section 4.5).
Do not use in patients with severe renal impairment (GFR <30 ml/min) (see Section 4.4).

4.4 Special warnings and precautions for use

Caution should be exercised in patients with:
- High blood pressure, heart disease, diabetes, thyroid disease, or trouble urinating due to enlarged prostate gland, arrhythmias, psychosis or phaeochromocytoma.
-A chronic cough as occurs with smoking or chronic lung disease such as asthma, chronic bronchitis, or emphysema.

There have been reports of acute systemic vasoconstrictive events with pseudoephedrine. Significant examples include:
- Acute Coronary Syndrome (ACS): Symptoms include sudden chest pain, tightness, heavy sweating and dyspnoea at rest.
- Ischaemic colitis: Symptoms include sudden abdominal pain and rectal bleeding.
- Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS): Symptoms included 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 of vasoconstrictive events develop.

Use with caution in patients taking vasoconstrictor agents such as ergot alkaloids (See Section 4.5).

Use with caution in patients taking beta-blockers or other anti-hypertensives (see Section 4.5).

Acute perioperative hypertension may occur if volatile halogenated anaesthetics are used simultaneously with indirect sympathomimetics. When planning surgery, it is recommended that pseudoephedrine treatment is stopped 24 hours before anaesthesia.

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

Caution is advised in patients over the age of 60 years. Patients in this age group are at greater risk of adverse reactions due to decreased renal function, and to experience unwanted reactions when using oral sympathomimetic agents.

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 Plus oral Solution should be discontinued and appropriate measures taken if needed.

Pseudoephedrine should be used cautiously in patients with severe hepatic impairment.

Pseudoephedrine should not be used by those with severe renal impairment
(Glomerular Filtration Rate – GFR <30 ml/min) (see Section 4.3) and should

be used with caution in those with moderate renal impairment (GFR 30-59 ml/min).

Ischaemic optic neuropathy
Ischaemic optic neuropathy has 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.

Excipient warnings:

- Patients with rare hereditary problems of fructose intolerance should not take this medicine because this product contains sorbitol and maltitol.
- 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.
- 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 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.
- 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.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administration of this medicine if the patient is taking a prescription monoamine oxidase inhibitor (MAOI) or is within the 14 days after stopping the MAOI drug is contraindicated because it may lead to hypertensive crisis.

The oxazolidinone class of antibiotics (including 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).

Concomitant use with sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like medicines) or tricyclic antidepressants may occasionally cause a rise in blood pressure (see Section 4.3).

Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa): pseudoephedrine may antagonise the effect of certain classes of antihypertensives (see Section 4.4).

Patients receiving cardiac glycosides or antihypertensive agents should be specifically directed on how to use this product. Pseudoephedrine may interact with halogenated anaesthetics (see Section 4.4). Vasoconstrictor agents, including ergot derivatives (such as bromocriptine, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine and methylsergide). Concomitant administration may cause an increased risk of ergotism (see Section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of the combination of guaifenesin and pseudoephedrine hydrochloride in pregnant women. Limited animal reproductive toxicity studies are available (see Section 5.3). As a precautionary measure, it is preferable to avoid the use of Robitussin Plus Oral Solution during pregnancy.

Breastfeeding
Pseudoephedrine is excreted in human breast milk in small amounts but the effect of this on breastfed infants is unknown. Decreased milk production in nursing mothers has been reported with pseudoephedrine. There is no data regarding the excretion of guaifenesin in human breast milk. Robitussin Plus Oral Solution should not be used during breastfeeding.

Fertility

There is no data on the effects of pseudoephedrine and guaifenesin on human fertility. Effects on male and female fertility have not been evaluated in animal studies.

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

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥ 1/10000 to <1/1000), very rare (<1/10000), not known (cannot be estimated from available data).

Whenever possible, adverse reactions observed in clinical trials and those reported from post marketing experience at therapeutic/labelled doses have been presented separately. These reactions are tabulated by MedDRA System Organ Class (SOC). As adverse reactions from post-marketing experience are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but considered likely to be rare or very rare.

The following side effects may be associated with the use of these active ingredients and are listed under their corresponding body system organ class:

Pseudoephedrine
The following adverse reactions have been reported with pseudoephedrine:

SystemOrgan Class	**AdverseReaction**	**Frequency**	

Immune System Disorders	Hypersensitivity	Not known	
Psychiatric Disorders	Nervousness, insomnia	Common	
	Agitation, restlessness	Uncommon	
	Hallucinations (particularly in children)	Rare	
	Anxiety	Not known	
Nervous System Disorders	Dizziness	Common	
	Headache, tremor	Not known	
	Posterior reversible encephalopathy syndrome (PRES) / Reversible cerebral vasoconstriction syndrome (RCVS)	Not known	
Eye Disorders	Ischaemic optic neuropathy	Not known	
Cardiac Disorders	Tachycardia, palpitations	Rare	
Vascular Disorders	Increased blood pressure1	Rare	
Gastrointestinal Disorders	Vomiting, dry mouth, nausea		Common
	Ischaemic colitis		Not known
Skin and Subcutaneous Tissue Disorders	Acute generalised exanthematous pustulosis (AGEP), allergic dermatitis2, rash	Rare	
Renal and Urinary Disorders	Dysuria, urinary retention3	Uncommon	

1Increases in systolic blood pressure havebeen observed. At therapeutic doses, the effects ofpseudoephedrine on blood pressure arenot clinically significant.
2A varietyof allergicskin reactions,with or without systemic features suchas bronchospasm and angioedema havebeen reported following useof pseudoephedrine.

3Urinaryretention is most likely tooccur in thosewith bladder outlet obstruction, such as prostatichypertrophy.

Guaifenesin
Post-Marketing Data

SystemOrganClass	**AdverseReaction**	**Frequency(from'notknown' toaproposedbelow)**
Immune System Disorders	Anaphylactic reactions, angioedema, hypersensitivity	Rare
Gastrointestinal Disorders	Vomiting, nausea, abdominal discomfort	Rare

Reportingof suspectedadverse 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 HPRA Pharmacovigilance website: www.hpra.ie

4.9 Overdose

Pseudoephedrine
Symptoms: pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation, e.g. excitement, restlessness, hallucinations, hypertension and arrhythmias. In severe cases, psychosis, convulsions, coma and hypertensive crisis may occur. Other symptoms may include nausea, vomiting, dizziness, tremor, anxiety, insomnia, irritability, nervousness.
Management: Treatment of pseudoephedrine overdose is symptomatic and supportive. Hypertension can be controlled with a beta-blocking agent.

Guaifenesin

Symptoms: very large doses can cause nausea and vomiting. **Management**: Vomiting would be treated by fluid replacement and monitoring of electrolytes.

Further management should be as clinically indicated or as recommended by the national poisons centres where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is used as an expectorant. It reduces the viscosity of the sputum.

Pseudoephedrine reduces swollen nasal membranes, tissue hyperaemia, oedema and nasal congestion. It increases nasal airway patency and reduces eustachian tube blockage.

5.2 Pharmacokinetic properties

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

Pseudoephedrine

Pseudoephedrine is absorbed from the GI tract. It is incompletely metabolised

in the liver. It is excreted both as unchanged pseudoephedrine and as metabolites in the urine.

Hepatic disease is unlikely to affect the pharmacokinetics of the drug. Normal adult dosage is appropriate (see Section 4.4)

Pseudoephedrine is primarily excreted by the kidneys. Renal impairment will result in increased plasma levels (see Section 4.4).

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 pseudoephedrine was orally administered to rabbits during organogenesis, no maternal or developmental toxicity was observed at a dose that was 1.3-fold greater than a clinical dose.

There are no experimental data available for guaifenesin from repeated dosing studies carried out over longer periods of time or from mutagenicity and carcinogenicity studies. A literature report showed reproductive toxicity in rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%)
Glycerol
Carmellose Sodium

Sodium Benzoate (E211)
Caramel (E150)**
Disodium Edetate
Amaranth (E123)
Citric Acid Anhydrous
Levomenthol
Maltitol Liquid (E965)
Natural Cherry Flavour*
Sorbitol Solution (70%) (E420)
Sodium Cyclamate
Acesulfame Potassium Salt
Purified Water
* contains ethanol (96%), propylene glycol and natural cherry flavour
** does not contain sucrose

6.2 Incompatibilities

None known.

6.3 Shelf life

PET bottles: 24 months

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

PET bottles containing 100ml 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

Haleon Ireland Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/154/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 July 1985

Date of last renewal: 29 July 2010

10 DATE OF REVISION OF THE TEXT

February 2024.