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

Taken orally.

Adults and children over 12 years: 10 ml x 3 daily

Children under 12: 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.

Persons with hypertension, acute ischaemic heart disease, glaucoma, thyrotoxicosis or urinary retention, should use this product ony as directed by a doctor.

Patients currently receiving, or who have received within two weeks, monoamine oxidase inhibitors.

Patients receiving other sympathomimetic agents or tricyclic antidepressants.

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.
- A chronic cough as occurs with smoking or chronic lung disease such as asthma or emphysema.

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.
It should be used only cautiously in patients with severe hepatic or renal impairment.

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.

Pregnant of lactating women should consult their doctor before use.
A doctor or healthcare professional should be sought if symptoms get worse or last more than 5 days, come back or are accompanied by fever, rash or persistent headaches. These could be signs of a serious condition.

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.

Keep out of reach of children.

Do not exceed recommended dose.

4.5 Interaction with other medicinal products and other forms of interactions

Do not take this product if you are taking a prescription monoamine oxidase inhibitor (MAOI) or for 14 days after stopping the MAOI drug.
Patients receiving cardiac glycosides or antihypertensive agents should use this product only as directed by a doctor.

4.6 Fertility, pregnancy and lactation

Consult a doctor before use.

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 these active ingredients and are listed under their corresponding body system organ class:

System Organ Class	**Frequency not known (cannot be Estimated from the available data)**
Immune system disorders	Hypersensitivity
Psychiatric disorders	Agitation, anxiety, excitability, insomnia, irritability, nervousness, restlessness
Nervous system disorders	Dizziness, headache, psychomotor hyperactivity
Cardiac Disorders	Palpitation, tachycardia
Vascular disorders	Hypertension, increased blood pressure
Gastrointestinal disorders	Nausea, vomiting, ischaemic colitis
Skin and subcutaneous tissue disorders	Rash, urticaria, severe skin reactions, including acute generalized exanthematous pustulosis (AGEP)

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 HPRA Pharmacovigilance website: www.hpra.ie

4.9 Overdose

The following side effects may be associated with an overdose of these actives ingredients:

Gastrointestinal disorders
Nausea, vomiting

Cardiac disorders
Bradycardia, palpitation, tachycardia

Nervous system disorders
Convulsion, dizziness, tremor

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

Vascular disorders
Hypertension, increased blood pressure

Skin and subcutaneous disorders:
Rash

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

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 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.

5.3 Preclinical safety data

Not applicable.

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

GlaxoSmithKline Consumer Healthcare (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 2021