

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Boots Pharmaceuticals Chesty Cough & Congestion Relief Oral Solution Guaifenesin 100 mg/5 ml Pseudoephedrine Hydrochloride 30 mg/5 ml

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Guaifenesin	100 mg
Pseudoephedrine hydrochloride	30 mg

Excipients: contains 1.77g sucrose and 0.3mg carmoisine per 5ml.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral solution  
Clear, bright purple syrup.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

An expectorant for the relief of chesty coughs, nasal congestion and catarrh without causing drowsiness.

For children aged 6 to 12 years: An expectorant for the relief of chesty coughs, nasal congestion and catarrh (without causing drowsiness) when simple measures have failed.

### 4.2 Posology and method of administration

For oral administration

Adults and children 12 years and over: 10ml four times a day.

Elderly: There is no need for dosage reduction in the elderly.

Children 6-12 years: 5ml three times a day.

This medicine is contraindicated in children under 6 years of age (see section 4.3).

Children of 6-12 years of age: not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment.

Warning: Do not exceed the stated dose.

Keep out of the sight and reach of children.

### 4.3 Contraindications

Hypersensitivity to the active substances or any of the excipients.

Severe renal impairment.

Cardiovascular disease including hypertension and ischaemic heart disease

Diabetes mellitus.

Phaeochromocytoma.

Hyperthyroidism.

Closed angle glaucoma.

Prostatic enlargement (patients with prostatic hypertrophy may have increased difficulty in micturition).

Urinary retention

Use in patients who are currently receiving other sympathomimetic drugs (such as other decongestants).

Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment, see section 4.5).

Beta-blockers – (See section 4.5).

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

#### **4.4 Special warnings and precautions for use**

##### **Guaifenesin**

Ask a doctor before use if you suffer from a chronic cough, if you have asthma or are suffering from an acute asthma attack.

Stop use and ask a healthcare professional if your cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache.

Do not take with a cough suppressant.

##### **Pseudoephedrine**

Caution in moderate to severe renal impairment.

If any of the following occur, this medicine should be stopped

Hallucinations

Restlessness

Sleep disturbances

If symptoms persist consult your doctor.

##### Severe Skin reactions

Severe skin reactions 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 Boots Pharmaceuticals Chesty Cough & Congestion Relief Oral Solution 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.

This product should be used with great care in patients suffering from angina and in patients receiving phenothiazines or tricyclic antidepressants.

This product may act as a cerebral stimulant giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

The physician or pharmacist should reassure himself that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

The label and leaflet will have a warning that for Children aged 6 to 12, parents/carers should seek the advice of the pharmacist or doctor first.

Information related specifically to the excipients in this formulation (see Section 6.1)

Sucrose. This medicine contains 1.77g sucrose per 5ml spoonful. This should be taken into account by patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine.

Carmoisine (E122) can cause allergic reactions.

#### **4.5 Interaction with other medicinal products and other forms of interactions**

##### **Pseudoephedrine**

MAOIs and/or RIMAs: should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis.

Moclobemide: risk of hypertensive crisis.

Antihypertensives (including adrenergic neurone blockers & beta-blockers): this medicine may block the hypotensive effects.

Cardiac glycosides: increased risk of dysrhythmias.

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension.

Oxytocin: risk of hypertension.

Enhances effects of anticholinergic drugs (such as TCAs). May increase the possibility of arrhythmias in patients taking tricyclic antidepressants.

Concomitant use with sympathomimetic agents such as decongestants and tricyclic antidepressants may occasionally cause a rise in blood pressure.

This product should be used with caution in patients receiving guanethidine, reserpine or methyl dopa.

Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

##### **Guaifenesin**

If urine is collected within 24 hours of a dose of guaifenesin 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**

The safety of this product during pregnancy and lactation has not been established, but in view of a possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, the use of the product during pregnancy should be avoided. The amounts of pseudoephedrine and guaifenesin secreted into breast milk are considered too small to be harmful.

#### **4.7 Effects on ability to drive and use machines**

No adverse effects known.

#### **4.8 Undesirable effects**

##### **Guaifenesin**

The following side effects may be associated with the use of guaifenesin:

Gastrointestinal disorders: nausea, vomiting, gastrointestinal discomfort.

Immune system disorders: hypersensitivity reactions.

##### **Pseudoephedrine**

Cardiovascular disorders: tachycardia, palpitations, other cardiac dysrhythmias. Very rarely, coronary vasospasm leading to myocardial ischaemia has been reported.

Gastrointestinal disorders: nausea and/or vomiting.

General disorders and administration site conditions: irritability.

Immune system disorders: hypersensitivity reactions, including cross-sensitivity that may occur with other sympathomimetics.

Nervous system disorders: headache, tremor, anxiety, restlessness, excitability, dizziness, insomnia, hallucinations (particularly in children) and paranoid delusions.

Psychiatric disorders: confusion and sleep disturbance.

Renal and urinary disorders: difficulty in micturition including urinary retention.

Skin and subcutaneous tissue disorders: skin reactions including rash. Frequency unknown - Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP).

Vascular disorders: hypertension. Very rarely, vasospasm associated with ischaemic colitis has been reported.

Eye disorders:

Frequency unknown: ischaemic optic neuropathy

### **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 HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie)

## **4.9 Overdose**

Symptoms of overdosage include irritability, restlessness, palpitations, hypertension, difficulty in micturition, nausea, vomiting, thirst and convulsions. In severe overdosage gastric lavage and aspiration should be performed. Symptomatic and supportive measures should be undertaken, particularly with regard to the cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

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

### **5.2 Pharmacokinetic properties**

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted in the urine unchanged.

It has an elimination half-life of 5 to 8 hours but its urinary elimination and hence half-life is pH dependent. Pseudoephedrine is rapidly distributed throughout the body, its volume of distribution being 2 to 3L/kg bodyweight.

Guaifenesin is readily absorbed from the gastrointestinal tract. It is rapidly metabolised and excreted in the urine.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber which are additional to that already included.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Liquid sugar (contains sucrose)

Hydroxyethylcellulose

Glycerol

Flav F menthol E43525

Acesulfame K

Potassium sorbate

Citric acid monohydrate

Sodium citrate

Food flav 511630E

Blackcurrant 17407107

Strawberry 500244E

Patent Blue V (E131)

14 October 2020

CRN009V6X

Page 4 of 5

Carmoisine edicol (E122)

Purified water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

2 years.

## **6.4 Special precautions for storage**

Do not store above 30 °C.

## **6.5 Nature and contents of container**

An amber PET bottle with a child resistant polypropylene cap fitted with an expanding polyethylene liner.  
A double ended polypropylene liner. A double ended polypropylene spoon with measures of 2.5ml and 5ml will be provided.

Pack sizes: 120ml, 150ml, 300ml

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

The Boots Company Plc  
1 Thane Road West  
Nottingham  
NG2 3AA  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA0004/054/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 12 May 2000

Date of last renewal: 12May 2010

## **10 DATE OF REVISION OF THE TEXT**

October 2020