SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Cough and Decongestant Syrup 6 Years +

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	% w/v
Guaifenesin	1.0
Pseudoephedrine hydrochloride	0.2

3. PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A combination expectorant and decongestant for the relief of acute productive (chesty) cough, nasal congestion and congestion of the mucous membranes of the upper respiratory tract associated with the common cold.

4.2 Posology and method of administration

For oral administration.

Children 6 to 12 years: Two 5ml spoonfuls three or four times a day.

Not more than 4 doses should be given in any 24 hours.

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 all medicines out of the sight and reach of children.

4.3 Contraindications

Hypersensitivity to the active substances or any of the excipients or intolerance to other sympathomimetics.
Severe renal impairment
Severe acute or chronic kidney disease/renal failure
Severe hypertension or uncontrolled hypertension
Cardiovascular disease including hypertension and peripheral vascular disease.
Diabetes mellitus

Phaeochromocytoma
Hyperthyroidism
Closed angle glaucoma
Concomitant use of other sympathomimetic 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 special 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

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

Hallucinations

Restlessness

Sleep disturbances

Caution in moderate to severe renal impairment.

Pseudoephedrine should be used with caution when administered to patients taking antihypertensive agents, tricyclic antidepressants, other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants. The effects of a single dose on the

blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.

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 Cough and Decongestant Syrup 6 Years + should be discontinued and appropriate measures taken if needed.

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

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.

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.

Do not give with any other cough and cold medicine.

If symptoms do not go away, talk to your pharmacist or doctor.

Information about the ingredients in this medicine

This medicine contains maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicine contains sorbitol. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

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The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

4.5 Interaction with other medicinal products and other forms of interaction

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, diuretics & beta-blockers): pseudoephedrine may block the hypotensive effects.

Cardiac glycosides: increased risk of dysrhythmias.

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

Appetite suppressants and amphetamine-like psycho-stimulants: risk of hypertension.

Oxytocin: risk of hypertension.

Enhances effects of anticholinergic drugs (such as TCAs).

Should not be given with other sympathomimetics such as decongestants, and thyroid hormones. Should not be given to patients undergoing general anaesthesia as them may induce 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

Pregnancy

There are limited amount of data on the use of pseudoephedrine in pregnant women. The use of pseudoephedrine during the first trimester of pregnancy

has been associated with an increased frequency of gastroschisis (a development defect in the abdominal wall with intestinal herniation) and of small intestinal atresia (congenital obstruction of small intestine). Due to the vasoconstrictive properties of pseudoephedrine, it may induce a reduction in uteroplacental circulation.
Pseudoephedrine is not recommended in pregnancy.

Breastfeeding
Pseudoephedrine has been detected in human milk with a small percentage of the maternal dose potentially administered to the breastfed infant. Irritability and disturbed sleep have been reported in breastfed infants. Pseudoephedrine may suppress lactation. Avoid if lactation not well established or if milk production is insufficient.
The amounts of 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 dysrythmias.

Eye disorders: Frequency unknown - Ischaemic optic neuropathy

Gastrointestinal disorders: nausea and/or vomiting, dry mouth.

Frequency unknown: Ischaemic colitis

General disorders and administration site conditions: irritability, thirst, tolerance with dependence has been reported with prolonged administration of pseudoephedrine-containing preparations.

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

Musculoskeletal and connective tissue disorders: muscular weakness.

Nervous system disorders: headache, giddiness, tremor, anxiety, restlessness, excitability, insomnia, hallucinations (particularly in children) and paranoid delusions. Frequency unknown - Posterior reversible encephalopathy syndrome (PRES) (see section 4.4), Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

Psychiatric disorders: sleep disturbance.

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

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

Vascular disorders: hypertension.

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

Symptoms of overdosage include headache, nausea, vomiting, tachycardia, urinary retention, hallucinations, coma, tremor, excitement, convulsions, respiratory depression, hypertension and arrhythmias.

Initial treatment consists of either emesis or gastric lavage, if appropriate. Otherwise treatment should by symptomatic and supportive, including the administration of a beta blocker if supraventricular tachycardia supervenes.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pseudoephedrine acts directly on both alpha and to a lesser extent beta adrenergic receptors. It is believed that the alpha adrenergic effects result from inhibition of the production of cyclic AMP by inhibition of the enzyme adenyl cyclase, whereas beta adrenergic effects result from stimulation of adenyl cyclase activity. Pseudoephedrine also has an indirect effect by releasing noradrenaline from its storage sites.

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

5.2 Pharmacokinetic properties

Pseudoephedrine is absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine
together with small amounts of its hepatic metabolite. It has an elimination half-life

of several hours.
Guaifenesin is readily absorbed from the gastrointestinal tract. It is metabolised and
excreted in the urine.

5.3 Preclinical safety data

Pseudoephedrine
There are no preclinical data of relevance to the prescriber which are additional to that
already included in other sections of the SPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol liquid
Hydroxyethyl cellulose
Glycerin
Purified water
Potassium sorbate
Acesulfame K
Sodium citrate
Citric acid monohydrate
Levomenthol
Alcohol 96%
Blackcurrant Flavour QL80001 (contains propylene glycol, may contain sulfites)
Vanilla Flavour Mixture QL78307 (may contain sulfites)

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

Amber PET bottle with polypropylene child resistant closure fitted with an expanded polyethylene liner.
Pack sizes: 100ml, 125ml, 150ml, 200ml

6.6 Instructions for use/handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Crest Medical Limited

Unit 5 Farrell Industrial Estate
Howley Lane
Warrington
WA1 2PB
UK

8 MARKETING AUTHORISATION NUMBER

PL 01021/0213

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 January 1997 / 30 January 2002

10 DATE OF REVISION OF THE TEXT

04/07/2025