SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chesty Cough & Congestion Relief Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	*/5 ml*
Guaifenesin Ph Eur	100 mg
Pseudoephedrine hydrochloride BP	30 mg

Excipients with known effect

carmoisine (E122)	0.3mg
liquid sugar (sucrose)	2ml

Flavours (containing sulphites, benzyl alcohol and ethanol)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A combination expectorant and decongestant for the relief of catarrh associated with acute productive (chesty) cough, nasal congestion and congestion of mucous membranes of the upper respiratory tract associated with the common cold without causing drowsiness.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years: 10ml (2 teaspoonfuls) four times a day.
Elderly: There is no need for dosage reduction in the elderly.
Children 6-12 years: 5ml (1 teaspoonful) 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 or 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.
Severe acute or chronic kidney disease/renal failure

Cardiovascular disease including hypertension or uncontrolled hypertension and peripheral vascular disease.
Diabetes mellitus.
Phaeochromocytoma.

Hyperthyroidism.
Closed angle glaucoma.
Should be avoided in patients with prostatic enlargement.
Concomitant use of other sympathomimetic decongestants (see section 4.5).
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

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 Chesty Cough & Congestion Relief Oral Solution 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.

If symptoms do not go away talk to your doctor.

Information about some of the ingredients
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

This medicine contains liquid sugar (sucrose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The colour carmoisine (E122) in this medicine may cause allergic reactions.

The flavourings in this medicine contain benzyl alcohol. This medicine contains 0.00002 mg benzyl alcohol in each 5 mL which is equivalent to 0.000003 mg/mL. Benzyl alcohol may cause allergic reactions. Caution should be taken with pregnant or breast feeding women, and patients with liver or kidney disease. This is because of the risk of accumulation and toxicity (metabolic acidosis).

The flavourings in this medicine contain alcohol (ethanol). This medicine contains less than 1 mg of alcohol (ethanol) in each 5 mL which is equivalent to less than 0.2 mg/mL. The amount in 5 mL of this medicine is equivalent to less than 1 mL beer or 1 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.

The flavourings and sucrose in this medicine contain sulphites. Sulphites may rarely cause severe hypersensitivity reactions and bronchospasm.

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 & beta-blockers): this medicine may block the hypotensive effects.**
Cardiac glycosides: increased risk of dysrythmias.
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).

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

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 developmental 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.

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 dysrhythmias.

Eye disorders: Frequency unknown - Ischaemic optic neuropathy

Gastrointestinal disorders: Nausea and/or vomiting.

Frequency unknown: Ischaemic colitis

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.

Frequency not known:

Posterior reversible encephalopathy syndrome (PRES) (see section 4.4)

Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

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.

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 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

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

Liquid sugar (contains sulphites)
Hydroxyethylcellulose
Glycerin
Flav F menthol E43525

Acesulfame K
Potassium sorbate
Citric acid monohydrate
Sodium citrate
Food flavour 511630E (Cream Flavour, contains sulphites, benzyl alcohol and ethanol (alcohol))
Blackcurrant flavour 17407107
Strawberry 500244E (contains sulphites, benzyl alcohol and ethanol (alcohol))
Patent Blue V
Carmoisine edicol
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months.

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 expanded polyethylene liner.

Pack sizes: 120ml

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 01021/0212

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/04/1997 / 02/05/2002

10 DATE OF REVISION OF THE TEXT

25/06/2025