Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Casacol Expectorant Syrup,
Methoxyphenamine hydrochloride, 20mg/5ml
Guaiphenesin, 100mg/5ml
Sodium Citrate, 200mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Methoxyphenamine hydrochloride	20 mg
Guaiphenesin	100 mg
Sodium citrate	200 mg

Also contains Sorbitol (E420), Ponceau 4R (E124), Nipasept [methyl (E128), ethyl (E214) and propyl (E216) Hydroxybenzoate]

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

A pale red straw coloured liquid with a faint odour of cherry, contained in an amber glass bottle.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Indicated in the treatment of cough and congestion associated with the common cold, bronchitis, etc.

Children aged 6-12 years: Casacol is indicated for second line use only.

4.2 Posology and method of administration

(a) Adults:

One or two 5ml spoonfuls 3 to 4 times daily.

(b) Children aged 6 to 12 years: 5ml 3 to 4 times daily.

Maximum daily dose: 20ml syrup.

Not more than 4 doses should be given in any 24 hours. Do not exceed stated dose. Use in children aged between 6-12 years should

be under the supervision of a healthcare professional (doctor/pharmacist). The duration of use should be restricted to no more than 5 days.

Use in children under 6 years is contra-indicated (see section 4.3).

4.3 Contraindications

1. Coronary thrombosis, hypertension, hyperthyroidism, closed-angle glaucoma and urinary retention.

2. Concurrent treatment with monoamine oxidase inhibitors, or within 10 days of stopping such treatment.

3. Concurrent treatment with other sympathomimetic drugs.

4. Sensitivity to the active ingredients or other product excipients (see section 6.1.)

5. In patients taking any other medicine for cough and cold.

6. Children under the age of 6 years.

4.4 Special warnings and precautions for use

1. This preparation should be used with caution in patients with organic heart disease or who are receiving digitalis therapy.

2. The preparation may precipitate urinary retention.

3. Patients with prostatic hypertrophy may have increased difficulty with micturition.

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

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

6. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

7. This preparation should be used with caution in patients with porphyria because guiaphenesin has been shown to be porphyrinogenic in animals.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of this product with sympathomimetic agents, such

as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants or with Monoamine Oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

The use of Casacol in patients currently receiving or who have received within 10 days monoamine oxidase inhibitors is contraindicated (see section 4.3).

This product should be used with caution in patients receiving digitalis therapy, beta-adrenergic blockers, guanethidine, resperine, methyldopa or anti-hypertensive agents.

Citrate salts taken orally can enhance the absorption of aluminium from the gastrointestinal tract. Patients with impaired renal function are particularly susceptible to aluminium accumulation and should avoid citrate containing oral preparations.

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

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Casacol in pregnant or lactating women. Casacol should not be used during pregnancy unless clearly necessary.

4.7 Effects on ability to drive and use machines

Casacol does not normally produce any effects on ability to drive or use machines.

4.8 Undesirable effects

Casacol may occasionally give rise to central nervous system stimulation, e.g. insomnia, nervousness, tremor and epileptiform convulsions.

In addition allergic reactions, urticaria, skin rashes (with or without irritation), itching, gastro-intestinal discomfort and urinary retention may occur.

Casacol contains the active ingredients methoxyphenamine HCl, guaiphenesin and sodium citrate. Methoxiphenamine is a sympathomimetic mixed-acting agent and the following additional adverse reactions have been reported for other sympathomimetics: tachycardia, impaired circulation to the extremities, hypertension, and cardiac arrhythmias.

Guaiphenesin, has been reported to cause gastro-intestinal discomfort, nausea and vomiting, and occasionally rash, urticaria,

dizziness and headache.

4.9 Overdose

The effects of acute toxicity from Casacol may include gastro-intestinal discomfort, nausea, vomiting, irritability, restlessness, tremor, convulsions, palpitations, hypertension and difficulty with micturition. Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if indicated. Catheterisation of the bladder may be necessary if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group – ATC R05 CA03, expectorants, excluding combinations with cough suppressants.

Methoxyphenamine hydrochloride is a sympathomimetic agent with preferential activity on beta-2 receptors. Guaiphenesin is an expectorant that reduces the viscosity of tenacious sputum.

Mechanism of Action

Methoxyphenamine hydrochloride is a direct acting sympathomimetic agent with a relatively selective action on beta-2 adrenoceptors. Stimulation of beta-2 adrenoceptors results in bronchodilation.

5.2 Pharmacokinetic properties

General Characteristics of the Active Substances

Methoxyphenamine hydrochloride is metabolised in the liver to O-desmethyl methoxyphenamine, N-desmethylmethoxyphenamine, and 5-hydroxy methoxyphenamine. This is mediated at least in part by an NADPH dependent CP_{450} system.

Guaiphenesin is readily absorbed from the gastrointestinal tract and is readily metabolised and excreted in the urine. The major urinary metabolite is beta-(2-methoxyphenoxy) lactic acid. Guaiphenesin has a plasma half-life of one hour.

Sodium citrate is metabolised, following absorption, to sodium bicarbonate and in the absence of a deficit of bicarbonate in the plasma, is excreted in the urine.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Saccharin sodium
Nipasept (methyl (E218), ethyl (E214) and propyl (E216) hydroxybenzoate)
Linctus flavour
Ponceau 4R (E124)
Sorbitol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Amber glass bottle with ROPP cap, containing 125ml or 300ml syrup.

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

Phoenix Labs
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Clonee
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1113/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd May 1979
Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

February 2014