Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mucodyne Paediatric Syrup 125 mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each of 5 ml of syrup contains 125 mg of Carbocisteine.

Excipients:
Also includes Sucrose 3.25g/5ml
Sodium Methylhydroxybenzoate (E219) 7.5mg/5ml
Red Ponceau 4R (E124) 0.25 mg/5ml
Ethanol 32mg/5ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

A red colour syrup with an odour and taste of raspberry and cherry.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Carbocisteine is a mucolytic agent for the adjunctive therapy of respiratory tract disorders characterised by excessive or viscous mucus.

4.2 Posology and method of administration

The route of administration is oral.

Recommended Dosage:
Children:
Children 2-5 years: 2.5 - 5ml four times daily
Children 5-12 years: 10ml - three times daily

4.3 Contraindications

Use in patients with a known hypersensitivity to Carbocisteine.
Use in patients with active peptic ulceration.
Use in patients below 2 years of age.

4.4 Special warnings and precautions for use

Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue medication.

Because of the possible effect on the mucous glands of the stomach, this product should be used with caution in patients with a history of peptic ulceration.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Carbocisteine is incompatible with Pholcodine Linctus, which causes precipitation of carbocisteine from solution.

4.6 Fertility, pregnancy and lactation

Although tests in mammalian species have revealed no teratogenic effects, Mucodyne should not be used during pregnancy unless considered essential by the physician.

Use in Lactation: Effects not known

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects include;
Gastrointestinal disorders
Frequency not known: nausea, gastrointestinal upset, vomiting, gastrointestinal bleeding

Nervous system disorders
Headache

Skin and subcutaneous tissue disorders
Allergic skin reactions and anaphylactic reactions, fixed drug eruption.
Isolated cases of dermatitis bullous such as Stevens-Johnson syndrome and erythema multiforme.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Gastric lavage may be beneficial, followed by observation. Gastro- intestinal disturbances is the most likely symptom of Mucodyne overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carbocisteine (S-carboxymethyl L-cysteine) has been shown in normal and bronchitic animal models to affect the nature and amount of mucus glycoprotein which is secreted by the respiratory tract. An increase in the acid:neutral glycoprotein ratio of the mucous and a transformation of serous cells to mucous cells is known to be the initial response to irritation and will normally be followed by hypersecretion. The administration of carbocisteine to animals exposed to irritants indicates that the glycoprotein that is secreted remains normal; administration after exposure indicates that return to the normal state is accelerated.

Studies in humans have demonstrated that carbocisteine reduces goblet cell hyperplasia. Carbocisteine can therefore be demonstrated to have a role in the management of disorders characterised by abnormal mucus.

5.2 Pharmacokinetic properties

Carbocisteine is rapidly absorbed from the GI tract. In an 'in-house' study, at steady state (7 days) Mucodyne capsules 375 mg given as 2 capsules t.d.s. to healthy volunteers gave the following pharmacokinetic parameters:

Plasma Determinations	*Mean*	*Range*
T Max (Hr)	2.0	1.0-3.0
T½ (Hr)	1.87	1.4-2.5
K_{EL} (Hr^{-1})	0.387	0.28-0.50
$AUC0_{0-7.5}$ ($mcg.Hr.ml^{-1}$)	39.26	26.0-62.4
Derived Pharmacokinetic Parameters		
*CL_S ($1\ Hr^{-1}$)	20.2	-
CL_S ($ml.min^{-1}$)	331	-
V_D (L)	105.2	-
V_D ($L\ Kg^{-1}$)	1/75	-

*Calculated from dose for day 7 of study

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium methyl hydroxybenzoate (E219)
Vanillin
Red ponceau 4R (124)
Cherry Flavour (contains ethanol and sugars)
Raspberry flavour (contains ethanol)
Sodium hydroxide solution
Hydrochloric acid
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

As packaged for sale: 1 year.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear PVC bottle with high density polyethylene cap, containing 300 ml of syrup, supplied with a graduated polypropylene dosage beaker.

Clear glass bottle (Type III) with tamper evident polypropylene cap with polyethylene liner, containing 300ml of syrup, supplied with a graduated polypropylene dosage beaker.

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

Ipsen Pharmaceuticals Limited
Blanchardstown Industrial Park
Blanchardstown
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0869/009/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1980
Date of last renewal: 11th June 2007

10 DATE OF REVISION OF THE TEXT

June 2017