Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Viscolex Syrup 250 mg / 5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral solution contains carbocisteine 250 mg.

Excipients
Each 5 ml contains: 3 g sucrose, 0.625 mg sunset yellow (E110), 4.5 mg sodium methyl parahydroxybenzoate (E219), 0.9 mg sodium ethyl parahydroxybenzoate (E215), 0.6 mg sodium propyl parahydroxybenzoate (E217) and <15 mg ethanol.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Clear, yellow, oral solution with odour and flavour of orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Viscolex Syrup is a mucolytic agent indicated in children over the age of 2 and also in adults. It is an adjunctive therapy in lower respiratory tract disorders characterised by excessive viscous mucous.

4.2 Posology and method of administration

Adults

The usual dosage is 15ml (750mg) 3 times daily initially, reducing to 10ml (500mg) 3 times daily when a satisfactory response has been obtained.

Children

6 – 12 years: The usual dosage is 5ml (250mg) two to three times daily.
2 – 5 years: The usual dose is 2.5ml (125mg) three times daily.

Under 2 years

Not recommended.

4.3 Contraindications

Hypersensitivity to carbocisteine or any of the excipients listed in section 6.1.

Patients with active peptic ulceration.

Children under 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.

When taken according to dosage recommendations the maximum daily dose supplies up to 27 g of sucrose.

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

Sunset yellow (E110) may cause allergic reactions.

This product contains orange flavour which contains small amounts of ethanol (alcohol), less than 15 mg per 5 ml dose.

This product contains 37.7 mg sodium per 5 ml and should be taken into consideration by people on a sodium controlled diet.

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.

Allergic reactions, possibly delayed, may be triggered by parahydroxybenzoates.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
This product should not be used during pregnancy unless considered essential by a physician.

Breast-feeding
There is no known data available on the effects of this product on breastfed infants.

Fertility
There is no known data available on the effects of this product on fertility in males or females.

4.7 Effects on ability to drive and use machines

No known effect on the ability to drive and use machines.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects: very common (≥ 1/10), common (≥ 1/100 < 1/10), uncommon (≥ 1/1,000 < 1/100), rare (>1/10,000, < 1/1,000), very rare (<1/10,000), unknown (cannot be estimated from the available data).

Immune system disorders
Unknown: Hypersensitivity reactions including rash, fixed drug eruption and anaphylaxis.

Nervous system disorders
Unknown: Headache.

Gastrointestinal disorders
Unknown: Nausea, gastric discomfort, diarrhoea, vomiting, gastro-intestinal bleeding.

Skin and subcutaneous tissue disorders
Unknown: Skin rash and allergic skin eruptions. Isolated cases of bullous dermatitis such as Stevens–Johnson syndrome and erythema multiforme have also been reported.

Paediatric population
Frequency and type of adverse reactions in children are expected to be the same as in adults.

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 followed by observation. Gastrointestinal disturbance will be a symptom of carbocisteine overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Respiratory system - Mucolytic
ATC code: R05CB03
Carbocisteine is a mucolytic agent.

Carbocisteine reduces the viscosity of non-infected secretion from mucous cells in the respiratory tract. It is rapidly and well absorbed from the gastric-intestinal tract. It appears to penetrate into the lung and respiratory mucous.

5.2 Pharmacokinetic properties

Carbocisteine is absorbed from the gastro-intestinal tract. After oral administration the subsequent kinetics fit a one-component open model. Peak serum concentrations were reached between 1 and 1.7 hours after oral administration and peak values after 1.5 g dose were 13.38 mg / litre. The plasma half-life was estimated to be 1.33 hours and the apparent volume of distribution was approximately 60 litres. No information is available on the extent of first-pass metabolism or protein binding. Carbocisteine appears to penetrate well into lung tissue and respiratory mucus suggesting a local action. The majority of the drug is excreted in the urine as unchanged drug and metabolites. There are no known pharmacokinetic studies on different paediatric age groups.

Carbocisteine is rapidly absorbed from the GI tract. In an 'in-house' study, at steady state (7 days) Mucodyne capsules 375mg 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
$AUC_{0-7.5}$ ($mcg.Hr.ml^{-1}$)	39.26	26.0-62.4

Derived Pharmacokinetic Parameters		
*CL_S ($L.Hr^{-1}$)	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

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sunset Yellow Colouring (E110)
Sodium Methyl Parahydroxybenzoate (E219)
Sodium Ethyl Parahydroxybenzoate (E215)
Sodium Propyl Parahydroxybenzoate (E217)
Disodium Edetate
Sodium Hydroxide
Glycerol (E422)
Orange Flavour (contains ethanol)
Critic Acid Monohydrate
Purified Water

6.2 Incompatibilities

None applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep container tightly closed.

6.5 Nature and contents of container

Type III, amber glass bottles with aluminium roll-on pilfer-proof screw caps, containing 100 ml or 250 ml of solution.

Not all pack sizes may be marketed.

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

Pinewood Laboratories Ltd., trading as Pinewood Healthcare
Ballymacarbry
Clonmel
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA0281/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th October 1986

Date of last renewal: 15th October 2006

10 DATE OF REVISION OF THE TEXT

January 2017