

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mucodyne 375 mg Capsules, Hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 375 mg of Carbocisteine.

Excipients: Each capsule contains sunset yellow (E110) and 22mg of lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, Hard (capsule).

Size No. 1 opaque, yellow, capsule, hard having an identification mark printed “mucodyne 375” in black ink and containing a white to almost white powder.

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:

Adults:

2 capsules three times a day initially, reduced to 1 capsule 4 times a day when a satisfactory response has been attained.

Children:

It is not recommended that this formulation be used for children.

4.3 Contraindications

1. Use in patients with a known hypersensitivity to Carbocisteine.
2. Use in patients with active peptic ulceration.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

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:

<i>Plasma Determinations</i>	<i>Mean</i>	<i>Range</i>
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
<i>Derived Pharmacokinetic Parameters</i>		
*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

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Aerosil 200 (colloidal silicone dioxide)
Lactose monohydrate (spray dried)
Sodium laurilsulfate

Capsule shell

Quinoline Yellow (E104)
Sunset Yellow (E110)
Titanium Dioxide (E171)
Gelatin

Printing Ink

Iron oxide black

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Securitainer: 5 years
Blister pack: 3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Grey HDPE bottles with white LDPE cap or child resistant cap, or grey polypropylene bottles with white LDPE cap or uPVC/PVdC/Aluminium blisters, containing 30, 100 or 120 capsules.

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

Ipsen Pharmaceuticals Limited
Blanchardstown Industrial Park
Blanchardstown
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0869/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th January 1975

Date of last renewal: 30th November 2007

10 DATE OF REVISION OF THE TEXT

June 2017