

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mucodyne 375 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocysteine 375 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsule

Yellow, size 1 capsules marked “MUCODYNE 375” in black and containing a white to off-white powder or friable plug.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Carbocysteine is a mucolytic agent for the adjunctive therapy of respiratory tract disorders characterised by excessive, viscous mucus, including chronic obstructive airways disease.

4.2 Posology and method of administration

Adults including the elderly:

Dosage is based upon an initial daily dosage of 2250mg Carbocysteine in divided doses, reducing to 1500mg daily in divided doses when a satisfactory response is obtained e.g. two capsules three times a day reducing to one capsule four times a day.

Children:

This formulation is not recommended for children. The normal daily dosage is 20mg/kg body weight in divided doses. It is recommended that this is achieved with Mucodyne Paediatric Syrup.

Mucodyne capsules are for oral use.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients.
Use in patients with active peptic ulceration.

4.4 Special warnings and precautions for use

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Although tests in mammalian species have revealed no teratogenic effects, Mucodyne is not recommended during the first trimester of pregnancy.

Use in lactation: Effects not known.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Immune System Disorders

There have been reports of anaphylactic reactions and fixed drug eruption.

Gastrointestinal disorders

There have been rare reports of gastrointestinal bleeding occurring during treatment with Mucodyne.

Skin and subcutaneous tissue disorders

There have been reports of skin rashes and allergic skin eruptions.

4.9 Overdose

Gastric lavage may be beneficial, followed by observation. Gastrointestinal disturbance is the most likely symptom of Mucodyne overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R05CB03

Carbocysteine (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 mucus and a transformation of serous cells to mucus cells is known to be the initial response to irritation and will normally be followed by hypersecretion. The administration of Carbocysteine 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 Carbocysteine reduces goblet cell hyperplasia. Carbocysteine can therefore be demonstrated to have a role in the management of disorders characterised by abnormal mucus.

5.2 Pharmacokinetic properties

Carbocysteine 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:

<u>Plasma Determinations</u>	<u>Mean</u>	<u>Range</u>
T Max (Hr)	2.0	1.0-3.0
T _{1/2} (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

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate (E572)
Silica, anhydrous colloidal (E551)
Lactose monohydrate (spray dried)
Sodium lauril sulfate
Size 1 yellow opaque gelatin capsules containing quinoline yellow (E104), sunset yellow (E110) and titanium dioxide (E171).

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Grey HDPE tamper-evident bottles with white LDPE cap or child resistant cap, or grey polypropylene securitainer bottles with white LDPE cap, containing 100 or 30 capsules. Blister packs of 120, 30, 18 or 6 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-aventis or SanofiOne Onslow Street
Guildford
Surrey
GU1 4YS
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 04425/0203

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

7 February 2009

10 DATE OF REVISION OF THE TEXT

17 October 2012