Mucodyne 375mg Capsules

Summary of Product Characteristics Updated 21-Sep-2021 | SANOFI

1. Name of the medicinal product

Mucodyne 375 mg Capsules, Hard

2. Qualitative and quantitative composition

Carbocisteine 375 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Capsule, hard

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

4. Clinical particulars

4.1 Therapeutic indications

Carbocisteine 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

Posology

Adults (including the elderly)

Dosage is based upon an initial daily dosage of 2250 mg Carbocisteine in divided doses, reducing to 1500 mg 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.

Paediatric population

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

Method of administration

Mucodyne capsules are for oral use.

4.3 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
- 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.

Excipient(s) with known effect

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

Lactose: 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 Fertility, pregnancy and lactation

Pregnancy

There are no available data on carbocisteine use in pregnant women. No conclusions can be drawn regarding whether or not carbocisteine is safe for use during pregnancy. The use of carbocisteine in pregnant women is not recommended, especially during the first trimester.

Breast-feeding

There are no available data on the presence of carbocisteine in human milk, milk production, or the effects on the breastfed infant. No conclusions can be drawn regarding whether or not carbocisteine is safe for use during breastfeeding. The use of carbocisteine in breastfeeding women is not recommended.

4.7 Effects on ability to drive and use machines

Mucodyne has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to ≤ 1/100); rare (≥ 1/10,000 to ≤ 1/1,000); very rare (≤ 1/10,000); not known (cannot be estimated from the available data).

Immune system disorders

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

Gastrointestinal disorders

There have been reports of diarrhoea, nausea, epigastric discomfort and gastrointestinal bleeding occurring during treatment with Mucodyne.

Frequency not known: vomiting, gastrointestinal bleeding

Skin and subcutaneous tissue disorders

There have been reports of skin rashes and allergic skin eruptions. Isolated cases of dermatitis bullous such as Stevens–Johnson syndrome and erythema multiforme have also been reported.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: respiratory system, mucolytics, ATC code: R05CB03

Mechanism of action

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 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 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
$AUC_{0-7.5}$ ($mcg.Hr.ml^{-1}$)	39.26	26.0 – 62.4

Derived Pharmacokinetic Parameters	Mean	Range
*CLS ($L.Hr^{-1}$)	20.2	-
CLS ($ml.min^{-1}$)	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 collodial (E551)

Lactose monohydrate (spray dried)

Sodium lauril sulfate

Size 1 yellow opaque gelatin capsules containing titanium dioxide (E171) and yellow iron oxide (E172).

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 tampertainer 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 and other handling

No special requirements.

7. Marketing authorisation holder

Aventis Pharma Limited

410 Thames Valley Park Drive

Reading

Berkshire

RG6 1PT

UK

Trading as:

Sanofi

410 Thames Valley Park Drive

Reading

Berkshire

RG6 1PT

UK

8. Marketing authorisation number(s)

PL 04425/0203

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 09 September 1974

Date of latest renewal: 12 February 2003

10. Date of revision of the text

15/06/2021

Company Contact Details

SANOFI

Address
Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

Medical Information Direct Line
+44 (0)800 035 2525

Telephone
+44 (0)118 354 3000

Medical Information e-mail
uk-medicalinformation@sanofi.com