Summary of Product Characteristics
(MUCOCORE)

1. NAME OF THE MEDICINAL PRODUCT
Carbocisteine Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 100 ml contains:
Carbocisteine BP……. 5 gm
In a flavored Syrup Base
Approved color used

For full list of excipients, see section 6.1

Composition

3. PHARMACEUTICAL FORM
Oral Liquid.

Description: Rose coloured clear syrup

Distribution Category: "Prescription only Medicine"

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 (300 ml presentation only)

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. for normal syrup 15 ml tds reducing to 10 ml tds.

Paediatric population (125 ml presentation only)

Children 2 – 5 years: The usual dose is 1.25 – 2.5 ml four times daily.

Children 5 – 12 years: The usual dose is 5 ml three times daily.

Method of administration
Mucodyne Syrup and Mucodyne Paediatric Syrup are for oral use.

4.3 Contraindications
• Hypersensitivity to the active substance(s) or to any of the excipients listed.

• Use in patients with active peptic ulceration.

• Mucodyne Paediatric Syrup is contraindicated for use in children less than 2 years of age.

4.4 Special warnings and precautions for use
For elderly patients, 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.

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

Warnings related Excipients used in the formulation

This product contains sorbitol and Glycerol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains Propylene Glycol, Sodium Methylhydroxybenzoate, Sodium benzoate and colour Ponceau 4R may cause allergic reactions (possible delayed).

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.

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
ATC code: R05CB03
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**
*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 section of the SmPC.

6. Pharmaceutical particulars
6.1 List of excipients
100 ml of CARBOCISTEINE SYRUP contains 5 g of Carbocisteine BP, Sodium Benzoate Methyl Paraben, Sorbitol (70% Non-Crystallizing), Glycerol, Propylene Glycol Citric Acid Monohydrate, Sodium Saccharine Sodium Hydroxide, Flavour Strawberry Crush (Vital), Menthol, Colour Ponceau 4R HIS.

6.2 Incompatibilities
None

6.3 Shelf life
36 months from the date of manufacturing.

6.4 Special precautions for storage
Do not store above 30°C. Protect from light
Once the bottle is opened it should be used within 3 months
Keep this medicine out of the sight and reach of children.

6.5 Nature and contents of container
Each pack contains a 100 millilitre Amber coloured pet bottle having red coloured clear syrup fitted with milky white colour aluminium PP cap with measuring cup and having printed label & packed in single printed carton with insert.

6.6 Special precautions for disposal and other handling
No special requirements.
7. MARKETING AUTHORISATION HOLDER
SANPRAS HEALTHCARE PVT. LIMITED
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Tel.: 02551-240266
E-mail: sanprashealth@rediffmail.com, info@sanprashealthcare.com
Website: www.sanprashealthcare.com

8. MARKETING AUTHORISATION NUMBER(S)
To be included after obtaining first registration.

8. Marketing Authorization Number
TAN 22 HM 0103

9. Date of first registration
11/04/2022

10. Date of Revision of the Text