Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mucotex 250 mg/5 ml syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains 250 mg carbocisteine.

Excipient(s) with known effect: each 5 ml of syrup contains 7.5 mg methyl parahydroxybenzoate (E218) and 2887.5 mg sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

Yellow- amber liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Carbocisteine is a mucolytic agent for the adjunctive therapy of respiratory tract disorders characterised by excessive and viscous mucus.

4.2 Posology and method of administration

Posology
Adults
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 3 times a day reducing to 10 ml 3 times a day.
Paediatric population
2 - 5 years: 1.25 - 2.5ml, four times a day.
6 - 12 years: 5 ml, three times a day.
Carbocisteine is contraindicated in children aged less than 2 years.

Method of administration
Use the measuring device to measure the appropriate amount, whether its use is for an adult or a child. The syringe for oral administration is graduated per 0.25ml. One graduation, 0.25ml corresponds to 12.5mg of carbocisteine.
How to use the syringe:
Step 1: Check the measurements on the side of the syringe to see how much to fill it.

Step 2: Push the syringe's plunger all the way down. Then put the tip of the syringe into the medicine bottle.

Step 3: Slowly pull back on the plunger until the syringe fills to the appropriate mark. Make sure there are not any large air bubbles in the syringe. If there are, empty the syringe and try again.

Step 4: Place the end of the syringe into the mouth against the cheek and carefully press the plunger down slowly to gently release the medicine. After use rep ace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of the reach of children.

4.3 Contraindications

Use in children less than 2 years of age.
Use in patients with active peptic ulceration.

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

4.4 Special warnings and precautions for use

Special precautions:
- Asthmatic patients with a history of bronchospasm;
- Severe respiratory failure;
- Debilitated patients. By decreasing the cough reflex there is a risk of obstruction of the airways as a consequence of the secretions amount increase.

The use of Mucotex implies a decrease in the mucus viscosity and removal, either through the ciliary activity of the epithelium, or by the cough reflex. Therefore it is expected an increase of cough and sputum. This association of this medicine with antitussive medication is not recommended.
Caution is advised in the administration of carbocisteine in individuals susceptible to gastroduodenal ulcers, as mucolytics have the capacity to destroy the gastric mucosal barrier.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase-isomaltase in sufficiency should not take this medicine.
This medicine contains methyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions have been identified.

4.6 Fertility, pregnancy and lactation

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

Breast-feeding
It is unknown whether carbocisteine/metabolites are excreted in human milk.

Fertility
There is no known relevant data available on the effects of carbocisteine on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse reactions listed by System Organ Class. Frequencies are defined using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 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).

System Organ Class	Frequency	Adverse reaction
Cardiac disorders		
	Rare	Palpitations
Endocrine Disorders		
	Not known	Hypothyroidism.*
Gastrointestinal disorders		
	Uncommon	Nausea, vomiting and diarrhea.
	Very rare	Gastrointestinal bleeding.
	Not known	Gastric discomfort.
Immune system disorders		
	Rare	Urticaria and bronchospasm.**
	Very rare	Rash.

Musculoskeletal and connective tissue disorders		
	Rare	Muscle pain
Nervous system disorders		
	Rare	Headache, dizziness, urinary incontinence, palpitations.
Respiratory, thoracic and mediastinal disorders		
	Rare	Shortness of breath.
	Not known	Bronchorrhea.
Skin and subcutaneous tissue disorders		
	Not known	Stevens-Johnsons syndrome, erythema multiforme.

* Special attention in patients with compromised thyroid function due to the risk of transient hypothyroidism occurrence.
** Special attention in asthmatic patients due to the risk of bronchoconstriction occurrence (contraction of a muscle of the bronchial wall that leads to a reduction in airflow). In these cases, treatment discontinuation is recommended.

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 to HPRA Pharmacovigilance:

HPRA Pharmacovigilance, website: www.hpra.ie

4.9 Overdose

Gastrointestinal disturbance (gastralgias, nausea and vomiting) are the most likely symptoms of Carbocisteine overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytic, ATC code: R05CB03

Carbocisteine (S-carboxy methyl L-c steine) 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 nor ally 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. Several studies 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. Equilibrium pharmacokinetics were established in healthy volunteers following administration of carbocisteine 375 mg capsules, 2 capsules t.d.s. for seven days. The mean Tmax was 2.0 hours (range 1.0 –3.0); T½ 1.87 hours (range 1.4 – 2.5); KEL 0.387 hour-1 (range 0.28 – 0.50) and AUC0-7.5 was 39.26 mcg.hr/m l (range 26.0 – 62.4). Values for derived pharmacokinetic values were CLS 331 ml.min-1; VD 105.2 L and VD 1.4 L/Kg.

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

Sucrose
Caramel (E150)

Gooseberry flavour
Sodium hydroxide (for pH- adjustment)
Methyl parahydroxybenzoate (E218)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
After opening, use within 3 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

200 ml or 300 ml type III amber glass bottles, with a white plastic inviolable closure HDPE/LDPE cap and a measuring device (oral syringe with polyethylene plunger and polyproplene cylinder with 5 ml capacity)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Amdeepcha (Malta) Ltd
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8 MARKETING AUTHORISATION NUMBER

PA23153/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th January 2019
Date of last renewal: 15th August 2022

10 DATE OF REVISION OF THE TEXT

September 2022