SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Carbocisteine <TRADE NAME> <STRENGTH> Syrup

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains <STRENGTH> of carbocisteine

For the full list of excipients, see section 6.1.

<REGARDING THE APPROVAL>

1. PHARMACEUTICAL FORM

Syrup <REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   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.

* 1. Posology and method of administration

**Posology**

**Adults including the elderly**

Dosage is based upon an initial daily dosage of 2250 mg in divided doses, reducing to 1500 mg daily in divided doses when a satisfactory response is obtained.

**Paediatric population**

Children 2 – 5 years: The usual dose is 62.5 – 125 mg four times daily.

Children 5 – 12 years: The usual dose is 250 mg three times daily.

Carbocisteine is contraindicated for use in children less than 2 years of age.

**Method of administration**

For oral administration.

* 1. Contraindications

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

Use in patients with active peptic ulceration.

Use in children less than 2 years of age.

* 1. 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 information**

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* 1. Interaction with other medicinal products and other forms of interaction

There are no known interactions with other medicinal products or other forms of interaction.

* 1. 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 breast-feeding. The use of carbocisteine in breast-feeding women is not recommended.

* 1. Effects on ability to drive and use machines

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

* 1. 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 carbocisteine.

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 Health Product Vigilance Center; HPVC.

* 1. Overdose

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

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytic, ATC code: R05C B03

Mechanism of action

Carbocisteine (5-carboxymethyl L-cysteine) has been shown in normal and bronchitic animal models to affect the nature and amount of mucus glycoprotein that 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 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 play a role in the management of disorders characterised by abnormal mucus.

* 1. Pharmacokinetic properties

**Absorption**

Carbocisteine is rapidly absorbed from the GI tract.

**Distribution**

Equilibrium pharmacokinetics were established in healthy volunteers following administration of carbocisteine 375mg 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/ml (range 26.0 – 62.4). Values for derived pharmacokinetic values were CLS 331ml.min-1; VD 105.2 L and VD1.4 L/Kg.

* 1. Preclinical safety data

No additional data of relevance to the prescriber.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

Not applicable.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>