SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Carbocisteine 375 mg Capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 375 mg of carbocisteine.

Excipient(s) with known effect:

Each capsule contains 8.5 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Size “1” hard gelatin capsule with yellow cap and yellow body containing a white to off white colour powder.

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 2250mg Carbocisteine 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 Carbocisteine Paediatric Syrup.

Method of administration:

Carbocisteine 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

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.

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

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

Breast-feeding

Use in lactation: Effects not known

Fertility

There is no consistent evidence on the effects of this product on fertility in males or females.

4.7 Effects on ability to drive and use machines

None stated.

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 and fixed drug eruption.

Gastrointestinal disorders:

There have been reports of 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 bullous dermatitis 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. Healthcareprofessionals are asked to report any suspected adverse reactions via Yellow Card Scheme at:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or AppleApp Store.

4.9 Overdose

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

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) Carbocisteine capsules 375mg given as 2 capsules t.d.s. to healthy volunteers gave the following pharmacokinetic parameters:

Plasma	Mean	Range
Determinations		

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

*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

Capsule content
Lactose monohydrate
Silica, colloidal anhydrous
Sodium lauryl sulphate
Magnesium stearate

Capsule shell
Gelatin
Purified water
Iron oxide yellow (E172)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Do not store above 25º C.

6.5 Nature and contents of container

Blister of 3x10's, 8x15's and 12x10's. Opaque ALU-PVC/PVDC blister pack.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Strandhaven Limited t/a Somex Pharma
Ilford, Essex
IG3 8BS.UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15764/ 0131

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/08/2021

10 DATE OF REVISION OF THE TEXT

08/02/2024