

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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $\leq 1/100$); rare ($\geq 1/10,000$ to $\leq 1/1,000$); very rare ($\leq 1/10,000$); 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. Healthcare professionals 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 Apple App 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:

<u>Plasma</u>	<u>Mean</u>	<u>Range</u>
<u>Determinations</u>		

T Max (Hr)	2.0	1.0-3.0
T _{1/2} (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

*CLs (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 25° 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

Package leaflet: information for the user

Carbocisteine 375 mg Capsules, hard

Carbocisteine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Carbocisteine Capsules are and what they are used for
2. What you need to know before you take Carbocisteine Capsules
3. How to take Carbocisteine Capsules
4. Possible side effects
5. How to store Carbocisteine Capsules
6. Contents of the pack and other information

1. What Carbocisteine Capsules are and what they are used for

Carbocisteine 375 mg Capsules, Hard (called Carbocisteine Capsules in this leaflet) contain a medicine called carbocisteine. This belongs to a group of medicines called 'mucolytics'. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up. Carbocisteine Capsules are used for problems with the breathing passages (respiratory tract). These problems happen when too much mucus is made or the mucus is too sticky.

2. What you need to know before you take Carbocisteine Capsules

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to carbocisteine or any of the other ingredients of Carbocisteine Capsules (listed in Section 6 below).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue

- You have an ulcer in your stomach or gut

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Carbocisteine Capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if

- You are elderly
- Have had an ulcer in your stomach or gut
- You are taking other medicines known to cause bleeding in the stomach

Children and adolescents

Children

Carbocisteine Capsules are not recommended for children. A syrup form of this medicine called 'Carbocisteine Paediatric 125 mg/5 ml Syrup' is available for use in children.

Adults (including the elderly)

- Usual dose is two capsules, 3 times each day
- If your symptoms improve, your dose should be lowered to one capsule, 4 times, each day

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This medicine should not be taken during the first three months of your pregnancy
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Important information about some of the ingredients of Carbocisteine Capsules

Carbocisteine Capsules contain:

- **Lactose.** This medicine contains lactose. This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Carbocisteine Capsules.

3. How to take Carbocisteine Capsules

Always take Carbocisteine Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- If you feel that this medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults (including the elderly)

- Usual dose is two capsules, 3 times each day
- If your symptoms improve, your dose should be lowered to one capsule, 4 times, each day

Children

- Carbocisteine Capsules are not recommended for children. A syrup form of this medicine called 'Carbocisteine Paediatric 125 mg/5 ml Syrup' is available for use in children

If you take more Carbocisteine Capsules than you should

If you take more Carbocisteine Capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. If you take too many Carbocisteine Capsules, it is likely that you will get an upset stomach (gastrointestinal disturbance).

If you forget to take Carbocisteine Capsules

If you forget a dose, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Carbocisteine Capsules can cause side effects, although not everybody gets them.

Stop taking Carbocisteine Capsules and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called

‘Stevens-Johnson syndrome’

- You have blood in your vomit or black tarry stools.

Tell a doctor straight away if you notice any of the following serious side effects:

- Blood in your vomit or black tarry stools

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Vomiting

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbocisteine Capsules

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Carbocisteine Capsules after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Carbocisteine contains

The active substance is carbocisteine

Each capsule contains 375 mg of carbocisteine.

The other ingredients are:

Capsule content: lactose monohydrate, silica colloidal anhydrous, sodium lauryl sulphate, magnesium stearate.

Capsule shell: gelatin, purified water, iron oxide yellow (E 172), titanium dioxide (E 171).

What Carbocisteine capsules looks like and contents of the pack

Each capsule contains 375 mg of carbocisteine.

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

Carbocisteine capsules are available in packs of 30 capsules and 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Somex Pharma

Ilford, Essex

IG3 8BS.UK

Manufacturer

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