Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Carbocisteine Teva 375mg capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 375 mg carbocisteine.

Excipients:
Lactose monohydrate (13.75 mg/capsule).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, hard
Turmeric yellow, size 1 gelatin capsules, hard, imprinted "6C1" on cap and "375" on body with black ink, containing white to off-white granular 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

For oral administration.

Adults including the elderly:
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. two capsules three times a day reducing to one capsule four times a day.

Children:
The capsule formulation is not recommended for use in children.

4.3 Contraindications

Hypersensitivity to carbocisteine or any of the other ingredients.
Use in patients with active peptic ulceration.

4.4 Special warnings and precautions for use

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Caution is recommended in patients with peptic ulcers.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Pregnancy
Studies in animals have shown no evidence of teratogenicity. Carbocisteine is not recommended during the first trimester of pregnancy.

Breastfeeding
There is no data on excretion of carbocisteine into breast milk.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The frequencies of adverse events are ranked according to the following: 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).

The following side effects have been reported:

Immune System Disorders
Frequency unknown: There have been reports of anaphylactic reactions and fixed drug eruption.

Gastrointestinal disorders
Rare: Nausea, diarrhoea
Very rare: Abdominal pain

Frequency unknown: There have been rare reports of gastrointestinal bleeding occurring during treatment with carbocisteine.

Skin and subcutaneous tissue disorders
Very rare: Allergic skin reactions such as pruritus, urticaria and rash

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

Pharmacotherapeutic group: Cough and cold preparations, mucolytics
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 one study, at steady state (7 days) carbocisteine 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
KEL (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	-
CLS ($ml.min^{-1}$)	331	-
VD (L)	105.2	-
VD ($L.Kg^{-1}$)	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

Lactose monohydrate
Sodium laurilsulphate
Silica, colloidal anhydrous
Magnesium stearate

Capsule cap/body:
Gelatin
Sodium laurilsulphate
Iron oxide yellow (E172)
Titanium dioxide (E171)

Printing Ink:
Shellac
Black iron oxide (E172)
Propylene glycol
Potassium hyroxide

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Aluminium/PVC/PE/PVdC blister pack containing 30, 100 or 120 capsules.
Polypropylene container with polypropylene screw cap (160 ml) containing 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

None stated.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
Brampton Road
Hampden Park
Eastbourne
East Sussex BN22 9AG
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA237/66/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th October 2012

10 DATE OF REVISION OF THE TEXT

May 2013