Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xtex 250 mg /5 ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral solution contains 250 mg of carbocisteine.

Excipients with known effect:
Maltitol (E 965): 750 mg per 5 ml
Propylene glycol (E 1520): 30 mg per 5 ml
Sunset yellow FCF (E 110): 0.03 mg per 5 ml
Sodium methyl parahydroxybenzoate (E 219): 7 mg per 5 ml
Sodium propyl parahydroxybenzoate (E 217): 1 mg per 5 ml

Total sodium content: 44.5 mg per 5 ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

Xtex is an orange-coloured transparent solution with an orange flavour.

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.
Xtex is indicated in adults and children aged 2 years and older.

4.2 Posology and method of administration

Posology

Recommended dosage:

Adults and children over 12 years:
The usual dose is 15ml three times daily initially, reducing to 10ml three times daily when a satisfactory response has been obtained.

Children 2 years and older:

The usual daily dose is 20mg/kg in divided doses.

Children 6-12 years: Usual dose is one 5ml teaspoon (250mg) two to three times daily
Children 2-6 years: Usual dose is half a 5ml teaspoon (125mg) two to three times daily.

Children under 2 years:

Not recommended.

Route of administration:
Oral use

Method of administration:
It is recommended to drink a glass of water after each dose and plenty of fluids during the day.

4.3 Contraindications

- Hypersensitivity to the active substance carbocisteine, other cisteine related compounds, or any of the excipients listed in section 6.1
- Should not be administered in patients with active gastroduodenal ulcer

4.4 Special warnings and precautions for use

Because of the possible effect on the mucous glands of the stomach, this product should be used with caution in patients with a history of peptic ulceration.

Notes on ingredients:
This medicinal product contains sunset yellow FCF (E 110) as an excipient.
May cause allergic-type reactions.

This medicinal product contains sodium methyl para-hydroxybenzoate (E 219) and sodium propyl para-hydroxybenzoate (E 217).
Can cause (possibly delayed) allergic reactions.

This medicinal product contains 44.5 mg of sodium per 5 ml, equivalent to 2.23 % of the WHO recommended maximum daily intake for sodium.
The maximum daily dose of this product is equivalent to 20.23% of the WHO recommended maximum daily intake for sodium.
Xtex is considered high in sodium. This should be particularly taken into account for those on a low salt diet.
This medicinal product contains 30 mg propylene glycol in each 5 ml dose.

This medicinal product contains maltitol (E 965).
Patients with rare hereditary problems of fructose intolerance should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Carbocisteine association with antitussives is not recommended. Simultaneous administration with an antitussive may cause inhibition of the cough reflex and may prevent the expulsion of fluidized mucus.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy and lactation unless considered essential by the physician.

Fertility:
No data.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse reactions are presented in order of decreasing seriousness within each frequency.
Very common (1/10) Common (1/100 <1/10) Uncommon (1/1000 <1/100) Rare (1/10000 <1/1000) Very rare (<1/10000) including isolated reports.

Gastrointestinal disorders:
Common: dyspepsia, nausea, vomiting, diarrhoea
They can occur especially at high doses. In these cases it may be useful to reduce the dose.
Rare: gastrointestinal haemorrhage

Nervous system disorders:
Rare: headache, dizziness

Skin and subcutaneous tissue disorders:
Rare: rash, pruritus
Very rare: fixed erythema

Immune system disorders:
Rare: hypersensitivity reactions
Very rare: bronchospasm

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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

In case of accidental massive ingestion, that can produce an intensification of adverse effects, mainly gastrointestinal, symptomatic treatment is recommended.
Gastric lavage may be beneficial, followed by observation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R05CB03
Pharmacotherapeutic group: Preparations for cough and cold, mucolytics.

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 mucous and a transformation of serious cells to mucous 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

Absorption
Carbocisteine is rapidly absorbed after oral administration. Peak plasma levels are reached 1 to 1.7 hours after oral administration.

Distribution
The kinetics of the process follows a one-compartment model. Carbocisteine has affinity for lung tissue and respiratory mucus, reaching maximum concentration in the mucus at 2 hours after oral administration.

Elimination
The plasma half-life of carbocisteine is 1.33 hours. The majority disposal occurs via the kidneys within 24 hours of administration, mainly as unchanged product (80%) or metabolites produced by acetylation and sulfoxidation decarboxylation. A small fraction is excreted in the feces (0.3%) and pulmonary route.

5.3 Preclinical safety data

In acute and repeated toxicity in animals, no significant toxicity has been demonstrated using much higher than therapeutic doses. There are no references to the possible occurrence of mutagenic, carcinogenic or affecting reproductive effects.

Preclinical safety data in literature have not revealed any relevant findings that have not been mentioned elsewhere in this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol (E 1520)
Sodium propyl parahydroxybenzoate (E 217)
Sodium saccharine
Citric acid monohydrate
Sodium methyl parahydroxybenzoate (E 219)
Liquid maltitol (E 965)
Sunset yellow FCF (E 110)
Hydroxyethylcellulose
Sodium citrate (E 331)
Orange flavour
Sodium hydroxide (E 524)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 Years.

This medicine should be used within 30 days after first opening.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

Amber-coloured Class III hydrolytic glass bottles fitted with a cylindrical white aluminium cap with text on the outer rim and glazed inside with a polyethylene seal.

Each presentation comes with a dose measurement cup.

Bottle content: 200 ml of solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Limited
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th July 2017
Date of last renewal: 13th July 2022

10 DATE OF REVISION OF THE TEXT

September 2022