Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Exputex 250mg / 5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of liquid contains 250 mg of Carbocisteine.

Excipients: Contains sunset yellow (E110), parahydroxybenzoates (E215, E217, E219), ethanol, and salts containing sodium.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution.

A viscous, orange coloured liquid with an odour of condensed milk and orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a mucolytic adjunct for respiratory tract disorders characterised by excessive or viscous mucous.

4.2 Posology and method of administration

For oral administration

Adults

The usual dose is three 5 ml spoonfuls three times daily initially, reducing to two 5 ml spoonfuls three times daily when a satisfactory response has been obtained.

Children

6-12 years: The usual dose is one 5ml spoonful (250 mg) two to three times daily.

2-5 years: The usual dose is half a 5ml spoonful (125 mg) two to three times daily.

Under 2 years: Not recommended.

4.3 Contraindications

Use in patients with a known hypersensitivity to carbocisteine or to any of the excipients in Exputex.

Use in patients with known active peptic ulceration.

4.4 Special warnings and precautions for use

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

Exputex contains approximately 100 mg sodium per 15 ml dose. To be taken into consideration by patients on a controlled sodium diet.

Exputex contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

Exputex contains sunset yellow FCF (E110) which may cause allergic reactions.

Exputex contains small amounts of ethanol, less than 100 mg per dose.

4.5 Interaction with other medicinal products and other forms of interaction

None listed.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None listed.

4.8 Undesirable effects

Reporting of 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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

Side effects include nausea, headache, gastrointestinal upset and skin rash.

4.9 Overdose

There is no experience of overdosing with this product and serious effects are not expected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mucolytic
ATC Code: RO5 CB03
Carbocisteine is a mucolytic agent.

5.2 Pharmacokinetic properties

Carbocisteine is absorbed from the gastrointestinal tract and excreted in the urine as unchanged drug and metabolites.

5.3 Preclinical safety data

None listed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Saccharin sodium
Sunset yellow FCF (E110)
Sodium ethyl parahydroxybenzoate (E215)
Sodium propyl parahydroxybenzoate (E217)
Sodium methyl parahydroxybenzoate (E219)
Citric acid monohydrate
Sodium hydroxide
Carmellose sodium
Glycerol
Levomenthol
Orange flavour 17.40.7040
Condensed milk flavour F7047
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Store the bottle in the original carton in order to protect from light.
Once opened use within one month.

6.5 Nature and contents of container

Amber glass bottle with polypropylene caps as closures.
Pack sizes: 100 ml, 200 ml, 300 ml.
A spoon with a 2.5ml and 5ml measure is supplied with all packs of this product.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
Suite 12
Bunkilla Plaza
Bracetown Business Park
Clonee
Co Meath

8 MARKETING AUTHORISATION NUMBER

PA1113/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 December 1985
Date of last renewal: 17 February 2010

10 DATE OF REVISION OF THE TEXT

January 2015