

# 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 with known effect

Each 5ml contains 20mg ethanol, 33.3mg sodium, 0.5mg sunset yellow, 1.16mg sodium ethyl parahydroxybenzoate, 5.40mg sodium methyl parahydroxybenzoate, 0.79mg sodium propyl parahydroxybenzoate, 15.10mg propylene glycol and salts containing sodium.

For the 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

Exputex is indicated in adults and children aged 2-12 years as a mucolytic adjunct for respiratory tract disorders characterised by excessive or viscous mucous.

### 4.2 Posology and method of administration

#### Posology

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.

Paediatric population 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 (125mg) two to three times daily.

Exputex oral solution is not recommended for children under 2 years of age.

#### Method of administration

For oral administration

### 4.3 Contraindications

Hypersensitivity to carbocisteine or to any of the excipients listed in section 6.1.

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.

### Excipients

This medicinal product contains approximately 33.3 mg sodium per 5 ml, equivalent to 1.7 % of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

This medicinal product contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

This medicinal product contains sunset yellow FCF (E110) which may cause allergic reactions.

This medicinal product contains 15.10mg of propylene glycol in each 5ml dose.

Exputex contains small amounts 20mg of alcohol (ethanol) in each 5 ml (which is equivalent to 4mg/ml)(0.4%w/v) The amount in 5ml dose of this medicinal product is equivalent to less than 1ml beer or 1 ml wine. The small amounts of alcohol will not have any noticeable effects.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed

#### **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**

There is no information to suggest that Exputex affects a patient's ability to drive or operate machinery.

#### **4.8 Undesirable effects**

Summary of the safety profile:

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

Reporting of suspected adverse reactions

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,

Website: [www.hpra.ie](http://www.hpra.ie);

#### **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: R05 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 (E 110)  
Sodium ethyl parahydroxybenzoate (E 215)  
Sodium propyl parahydroxybenzoate (E 217)  
Sodium methyl parahydroxybenzoate (E 219)  
Citric acid monohydrate  
Sodium hydroxide  
Carmellose sodium  
Glycerol  
Levomenthol  
Orange flavour (containing propylene glycol )  
Condensed milk flavour (containing propylene glycol (E1520) )  
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years.

### 6.4 Special precautions for storage

Do not store above 25 °C.  
Keep the bottle in the outer carton in order to protect from light.

### 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.  
Not all pack sizes may be marketed

### 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.

### 6.6 Special precautions for disposal

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Phoenix Labs Unlimited Company  
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Clonee  
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**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**

October 2026