

### 1.3.1.1 Current Approved Professional Information for Medicines for Human Use

#### SCHEDULING STATUS

S2

#### 1. NAME OF THE MEDICINE

BETAPHLEM SYRUP

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains:

Carbocisteine 250 mg

Contains sugar:

Sucrose: 1,9 g / 5 ml

Glycerin: 390 mg / 5 ml

Preservatives:

Methyl hydroxybenzoate 0,17 % *m/v*

For full list of excipients, see section 6.1

#### 3. PHARMACEUTICAL FORM

Syrup

Red, syrupy liquid with a sweet cherry flavor

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Adjunctive therapy in respiratory tract disorders characterised by excessive viscous mucous in the absence of infection.

##### 4.2 Posology and method of administration

Not recommended for children under 2 years.

Adults: Two to three medicine measures (10 ml to 15 ml), three times daily.

Children: 6 - 12 years: One medicine measures (5 ml) three times daily.

Children: 2 - 5 years: A quarter to half a medicine measures (1,25 - 2,5) ml four times daily, according to age.

#### **4.3 Contraindications**

- Hypersensitivity to carbocisteine, or to any of the excipients listed in **section 6.1**.
- Active peptic ulcer.
- The safety in pregnancy has not been established.
- Incompatible with pholcodeine linctus.

#### **4.4 Special warnings and precautions for use**

**BETAPHLEM SYRUP** should be administered with caution to patients with a history of peptic ulcer and should be avoided in patients with active ulceration.

- In patients with a history of gastric or duodenal ulcer;
- Asthmatic patients with a history of bronchospasm;
- Severe respiratory failure;
- Debilitated patients. By decreasing the cough reflex there is a risk of obstruction of the airways as a consequence of the secretions amount increase.

The use of carbocisteine implies a decrease in the mucus viscosity and removal, either through the ciliary activity of the epithelium, or by the cough reflex. Therefore it is expected an increase of cough and sputum. This association of this medicine with antitussive medication is not recommended.

Caution is advised in the administration of carbocisteine in individuals susceptible to gastroduodenal ulcers, as mucolytics have the capacity to destroy of the gastric mucosal barrier.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains methyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

#### **4.5 Interaction with other medicines and other forms of interaction**

Incompatible with pholcodeine linctus.

#### **4.6 Fertility, pregnancy and lactation**

The safety of **BETAPHEM SYRUP** in pregnancy has not been established.

Breast-feeding

It is unknown whether carbocisteine/metabolites are excreted in human milk.

Fertility

There is no known relevant data available on the effects of carbocisteine on fertility.

#### **4.7 Effects on ability to drive and use machines**

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

#### 4.8 Undesirable effects

<b>System Organ Class</b>	<b>Less frequent</b>	<b>Frequency Unknown</b>
<b>Cardiac disorders</b>	Palpitations	
<b>Endocrine disorders</b>		Hypothyroidism
<b>Gastrointestinal disorders</b>	Nausea, vomiting, diarrhoea, gastrointestinal bleeding	Gastric discomfort
<b>Immune system disorders</b>	Urticaria, bronchospasm, rash	
<b>Musculoskeletal and connective tissue disorders</b>	Muscle pain	
<b>Nervous system disorders</b>	Headache, dizziness, urinary incontinence, palpitations	
<b>Respiratory, thoracic and mediastinal disorders</b>	Shortness of breath	Bronchorrhea
<b>Skin and subcutaneous tissue disorders</b>		Steven-Johnsons syndrome, erythema multiforme

#### 4.9 Overdose

Refer to side-effects and special precautions. Treatment is supportive and symptomatic.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Category A.10.3 Medicines acting on respiratory system: Other

Pharmacotherapeutic group: Mucolytic, ATC code: R05CB03

**BETAPHLEM SYRUP** reduces the viscosity of non-infected secretions from mucous cells in the respiratory tract.

### 5.2 Pharmacokinetic properties

Carbocysteine is rapidly absorbed from the GI tract.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Cherry essence no.1
- Citric acid
- Glycerin
- Hydrochloric acid
- Methyl hydroxybenzoate
- Poncea 4R Supra (W.G. 709) C.I. 16255
- Sodium citrate
- Sodium hydroxide
- Sucrose
- Water, purified

### 6.2 Incompatibilities

Not applicable

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

Store in a cool place, at or below 25 °C. Protect from light.

### **6.5 Nature and contents of container**

200 ml and 2,5 litre bottles.

### **6.6 Special precautions for disposal <and other handling>**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. HOLDER OF CERTIFICATE OF REGISTRATION**

RANBAXY PHARMACEUTICALS (PTY) LTD

14 LAUTRE ROAD

STORMILL EXT. 1

ROODEPOORT

1724

SOUTH AFRICA

## **8. REGISTRATION NUMBER(S)**

S/10.2.2/146 (S.A.)

B9314865 (Botswana)

1208 (Mozambique)

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31 July 1985

**10. DATE OF REVISION OF THE TEXT**

31 August 2022