SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

## 1. NAME OF THE MEDICINAL PRODUCT

Carbocisteine Syrup 5%

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains:

Carbocisteine BP…….250 mg

Flavoured base ……q,s.

Colour : Sunset Yellow FCF

For complete list of excipients refer section 6.1

## 3. PHARMACEUTICAL FORM

Liquid Oral Dosage Form- Syrup.

## 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 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. for normal syrup 15ml tds reducing to 10ml tds.

**Children:**

This medicine is not recommended for use in children and adolescents under the age of 18 years due to alcohol content.

## 4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Use in patients with active peptic ulceration.

Use in children less than 2 years of age.

## 4.4 Special warnings and precautions for use

Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue medication.

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

**Special Warnings And Precautions For Use:**

This Syrup contains sucrose and sorbitol, hence it is unsuitable for those patients who have inherited fructose intolerance, glucose - galactose malabsorption syndrome of sucrase - isomaltase deficiency.

This preparation contains methyl Hydroxybenzoate, propyl Hydroxybenzoate and, colour Sunset yellow which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm

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.

Sodium: Talk to your doctor or Pharmacist if you need 44ml or more syrup daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Sodium Benzoate: This medicine contains 5mg Sodium Benzoate in each 5ml. it may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Propylene Glycol: This medicine contains 250mg Propylene Glycol in each 5ml.

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

Interaction with other medicines none stated.

## 4.6 Pregnancy and Lactation

**Pregnancy**

There are no available data on carbocisteine use in pregnant women. No conclusions can be drawn regarding whether or not carbocisteine is safe for use during pregnancy. The use of carbocisteine in pregnant women is not recommended, especially during the first trimester.

**Breast-feeding**

There are no available data on the presence of carbocisteine in human milk, milk production, or the effects on the breastfed infant. No conclusions can be drawn regarding whether or not carbocisteine is safe for use during breastfeeding. The use of carbocisteine in breastfeeding women is not recommended.

**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**

Immune System Disorders: there have been reports of anaphylactic reactions (rare). Skin and Subcutaneous Tissue Disorders: there have been reports of skin rashes and allergic skin eruptions.

Gastrointestinal disorders: abdominal pain, nausea, diarrhea, gastrointestinal bleeding.

In case of such adverse effects recommended to reduce dose or stop taking the medication.

**4.9 Overdose**

**Symptoms:** Abdominal pain,nausea, diarrhea,

**Treatment:** appropriate symptomatic treatment is indicated.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1** Pharmacodynamics properties

Pharmacotherapeutic group: Mucolytic and expectorant agents, 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

Carbocisteineis rapidly absorbed from the gastrointestinal tract, peak plasma concentrations are reached after about hour(pH 7-9). Bioavailability is low, less than 10%, probably, due to the metabolism in the gastrointestinal tract and “first pass” through the liver.

Carbocisteine is excreted primarily by the kidneys. The half-life is about 2 hours.

## 5.3 Preclinical safety data

There are no preclinical data.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Each 5 ml of Carbocisteine 5% syrup for children contains:

Active ingredient: carbocisteine-250mg;

Excipients: Sucrose (sugar pharma grade), Sodium hydroxide, Flavor caramel, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sodium benzoate, Flavour essence vanilla, Flavour essence ice cream soda, Colour sunset yellow FCF supra, Citric acid anhydrous, Disodium Edetate, Sorbitol 70 % (non crystallizing), Propylene glycol, Hyflosupercel, Purified water

### 6.2 Incompatibilities Not

Applicable

### 6.3 Shelf life

36 Months

### 6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Protect From Light.

Keep the medicine out of reach of children.

### 6.5 Nature and contents of container <and special equipment for use, administration or implantation>

125 mL, Amber coloured PET round bottles with 25 mm ROPP caps with EP wad pack into printed carton along with a leaflet.

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

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

## 7. APPLICANT/MANUFACTURER>

**Manufactured by:**

SKant

HEALTHCARE Ltd.

**1802-1805, G.I.D.C., Phase III,**

**Vapi - 396 195. Gujarat, INDIA.**