SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Carbocisteine Syrup 2%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains:

Carbocisteine BP…….100 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

The recommended dose for children 2-6 years is 2.5-5 ml syrup for children (half or one teaspoon), every 6 hours, for children 6-12 years 10 ml syrup for children (two teaspoons) every 8 hours.

Duration of treatment usually does not exceed 8-10 days.

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.

Carbocisteine Syrup is contraindicated for use in children less than 2 years age.

4.4 Special warnings and precautions for use

Carbocisteine should be used with caution in patients with wet cough.

It should be used with caution in patients with gastric and duodenal ulcer. Carbocisteine shouldn't be given with antitussive drugs and /or with drugs depressing bronchial secretions (including atropine – like drugs).

In the case of prescription of drug in patents having diabet, or in patents being on a diet with low sugar content, should be considered the sugar content (5.25 g per tablespoon).

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 2% syrup for children contains:

Active ingredient: carbocisteine-100mg;

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:

SKKant

HEALTHCARE Ltd.

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

Vapi - 396 195. Gujarat, INDIA.