SUMMARY PRODUCT CHARACTERISTIC (SPC)

CARBOCISTEINE
2% SYRUP FOR CHILDREN

TRADE NAME – Carbocisteine 2 % syrup for children
INTERNATIONAL NON-PROPERTY NAME – Carbocisteine

COMPOSITION
Each 5 ml of Carbocisteine 2% syrup for children contains:

active ingredient:carbocisteine-100 mg;
inactive ingredients: sodium saccharin, propylene glycol, sucrose, methylparaben, aroma caramel, sodium hydroxide, color yellow E 110,water deionized.

CHEMICAL NAME AND CAS NUMBER
(2R)-2-amino-3-[(carboxymethyl)sulphanyl]propanoic acid , 2387-59-9.

PHARMACOLOGICAL GROUP AND ATC CODE
Mucolytic agent. ATC code R05CB03.

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
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.

Pharmacokinetic properties
Carbocisteine is 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.

USES
Violations of bronchial secretions (including acute bronchitis and acute exacerbations of chronic diseases of the bronchi and lungs).

DOSAGE AND 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.

ADVERSE 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.

CONTRAINDICATIONS
- Hypersensitivity to carbocisteine or to any of the excipients in anamnesis.
- Use in patients with active peptic ulceration.
- Children under 2 years old.

PRECAUTIONS
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 (1.75 g per teaspoon).
Medicine contains methylparaben which may cause allergic reactions (possibly delayed).
Medicine contains propylene glycol which at 50 mg/kg/day, If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.
Medicine contains color yellow E 110 which may cause allergic reactions.

PREGNANCY AND BREAST FEEDING
Carbocisteine should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.
Breastfeeding should be suspended during treatment with Carbocisteine.

OVERDOSAGE
Symptoms: Abdominal pain, nausea, diarrhea.
Treatment: appropriate symptomatic treatment is indicated.

DRUG INTERACTIONS
Interaction with other medicines none stated.

PRESCRIPTION STATUS
To be dispensed without prescription.

IDENTIFICATION
A clear yellow colored, caramel flavored syrup.

PRESENTATION
120 ml of syrup is filled into amber glass bottles (inside package).
The bottles are packed and inserted with the leaflet into cardboard boxes (outer package).

STORAGE CONDITIONS
Store at a temperature not higher than 25°C, in a dry place, out of the reach of children. Protect from light.

EXPIRY DATE

3 years.

MANUFACTURER
“ARPIMED” LLC
Bldg. 19, mcr 2-nd, Abovyan, Kotayki Marz, Republic of Armenia
Tel.: (374) 222 21703 Fax: (374) 222 21924

MARKETING AUTHORIZATION HOLDER
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