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
FOR CHILDREN (from 2 years old).
Dosage
The dosage for children aged 2 to 5 years is 200 mg per day, divided in 2 doses, i.e. 5 ml syrup twice a day.
The dosage for children over 5 years of age is 300 mg per day, divided into 3 doses, i.e. 5 ml syrup 3 times a day.
Duration of treatment
Do not exceed 8 to 10 days of treatment without medical advice from your doctor.

Method of administration
Oral.

ADVERSE EFFECTS

- Risk of bronchial congestion in infants.
- Epigastric discomfort.
- Gastrointestinal disorders (gastralgia, nausea, vomiting, diarrhoea). It is then recommended to reduce the dose.
- Gastrointestinal bleeding. It is recommended to stop treatment.
- Allergic skin rashes and anaphylactic reactions such as pruritus, erythematous rash, urticaria and angioedema.
- Fixed eruption of drug origin.
- A few cases of fixed pigmented erythema have been reported.
- Isolated cases of bullous dermatoses such as Stevens-Johnson syndrome and erythema multiforme.

Reporting of suspected adverse reactions
Reporting 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 ″Arpimed″ LLC by going to www.arpimed.com and fill out the appropriate form ″Report an adverse reaction or inefficiency of drug″. Hotline number: (+374 55) 05 79 86. And by using ″Centre of Drug and Medical Technology Expertise″ SNPO, going to the site: www.pharm.am in ″Report about adverse effect of medicine″ section and fill out the ″Report of adverse reaction or manufacturing problem of medicinal product″.
Hotline numbers: +37410200505; +37496220505.

CONTRAINDICATIONS

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

PRECAUTIONS

Special warnings
In case of wet and purulent expectoration, in case of fever or in case of chronic disease of the bronchi and lungs, re-examine the clinical situation.
Productive coughs, which represent a fundamental element of bronchopulmonary defense, must be taken in account.
Concomitant use of mucomodifiers with antitussive medicines and/or medicines that inhibit bronchial secretion (atropinics) is not recommended.
Mucolytics may cause bronchial congestion in infants. Indeed, their bronchial mucus drainage capacities are limited, due to the physiological characteristics of their respiratory tract. They should therefore not be used in children below 2 years.
Treatment should be reassessed if symptoms or disease persist or worsen.

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.
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 E110 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Carbocisteine syrup has no or negligible influence on the ability to drive and use machines.

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
2% syrup for children in 120 ml bottles together with a leaflet in a cardboard box.

STORAGE CONDITIONS
Store out of reach of children, in a dry, protected from light place at a temperature below 25°C.

EXPIRY DATE
3 years.

MARKETING AUTHORIZATION HOLDER
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