SUMMARY PRODUCT CHARACTERISTIC (SPC)

CARBOCISTEINE 5 % SYRUP FOR ADULTS

TRADE NAME – Carbocisteine 5 % syrup for adults
INTERNATIONAL NON-PROPERTY NAME – Carbocisteine

COMPOSITION

Each 5 ml of Carbocisteine 5% syrup for adults contains:
active ingredient: carbocisteine - 250 mg;
inactive ingredients: sodium saccharin, propylene glycol, sucrose, methylparaben, aroma caramel, sodium hydroxide, color yellow E 110, water purified.

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

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.

USES

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

DOSAGE AND ADMINISTRATION

FOR ADULTS AND ADOLESCENTS OVER 15 YEARS OF AGE ONLY.
Dosage
Take 1 dose of 15 ml, which contains 750 mg carbocisteine, 3 times a day, preferably between meals.
Duration of treatment
The duration of treatment should be short and not exceed 5 days.
Method of administration
Oral.

ADVERSE EFFECTS

- 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 urticaria, angioedema, pruritus, erythematous rash.
- 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.

PRECAUTIONS

Special warnings

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.

Precautions for use

Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, or those taking concomitantly 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 (5.25 g per tablespoon).
Medicine contains methylparaben which may cause allergic reactions (possibly delayed).
Medicine contains color yellow E 110 which may cause allergic reactions.
This medicinal product contains 96.88 mg sodium per 15 ml, equivalent to 4.84 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

PREGNANCY AND BREAST FEEDING

Carbocisteineshould 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 medicins none stated.

PRESCRIPTION STATUS
To be dispensed without prescription.

IDENTIFICATION
A clear yellow colored, caramel flavored syrup.

PRESENTATION
5% syrup for adults 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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