File information

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Technical colors

Diecut-Legendcase		Free area		Glue points		

2% Carbocisteine

Rhinathiol Children

Syrup

NAME AND STRENGTH
- The active substance is: Carbocisteine 2 g for 100 ml. One 5 ml measuring spoon contains 100 mg of carbocisteine.
- The other ingredients are: Sucrose, methyl parahydroxybenzoate (E218), vanillin, cochineal red A (E124), raspberry flavoring, cherry flavoring, sodium hydroxide, purified water.

PRODUCT DESCRIPTION
Red syrupy liquid with an odour of raspberry and cherry.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: MUCOLYTICS, ATC code: R05CB03. (R: respiratory system).
Carbocisteine has a mucolytic effect on bronchial secretions. It acts on the gel phase of mucus production, most likely by breaking down the disulfide bonds in the glycoproteins, thus promoting expectoration.

Pharmacokinetic properties
Absorption
Orally administered carbocisteine is rapidly absorbed; peak plasma concentrations are reached in two hours.

Biotransformation
Bioavailability is low (less than 10% of the administered dose), probably as a result of intraluminal metabolism and a marked liver first-pass effect.

Elimination
Elimination half-life is approximately 2 hours. Carbocisteine and its metabolites are eliminated primarily in the urine.

Preclinical safety data
Not applicable.

INDICATIONS
Treatment of bronchial secretion disorders, particularly in acute bronchial disease: acute bronchitis and acute episodes of chronic obstructive pulmonary disease.

DOSAGE AND METHOD OF ADMINISTRATION
One 5 mL measuring spoon contains 100 mg of carbocisteine.
Children aged 2 to 5 years: 200 mg per day, divided into 2 doses, i.e. one 5 mL measuring spoon twice a day.
Children aged over 5 years: 300 mg per day, divided into 3 doses, i.e. one 5 mL measuring spoon three times a day.

Duration of treatment
Treatment duration should be short and not exceed 8 to 10 days.

CONTRAINDICATIONS
- History of hypersensitivity to any of the ingredients (particularly methyl parahydroxybenzoate and other parahydroxybenzoate salts)
- In case of active gastroduodenal ulcer.
- Contraindicated in children below two (2) years of age.

WARNINGS AND PRECAUTIONS
Special warnings
In patients with thick and purulent sputum, fever or chronic bronchial and pulmonary disease, the clinical situation should be reassessed.

Productive cough, which is a fundamental bronchopulmonary defense mechanism, should not be suppressed.

Combining drugs that affect bronchial secretions with cough suppressants and/or substances that dry up secretions (atropine-like agents) is irrational.

Mucolytic agents may induce severe bronchial congestion in infants. Infant bronchial mucus drainage capacities are limited due to the physiological characteristics of their bronchial tree. Mucolytics should therefore not be used in infants (see sections Contraindications and Side Effects).

Treatment should be re-evaluated if the 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.

Excipients with known effect:
This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 3.5 g of sucrose per measuring spoon. This should be taken into account in patients following a low-sugar diet or with diabetes mellitus.

This medicine contains sodium. This medicine contains 13 mg sodium in each 5 mL measuring spoon of syrup. This should be taken into account in patients following a strict low-sodium diet.

This medicine contains methyl parahydroxybenzoate (E 218) and cochineal red A (E124) it may provoke allergic reactions (possibly with a delayed onset).

This medicine contains 31 mg of ethanol per 5 mL measuring spoon, which is equivalent to 6.2 mg/mL (0.62% w/v). The amount of ethanol in 5 mL of this medicine is equivalent to less than 1 mL of beer or less than 1 mL of wine.

The small amount of alcohol in this medicinal product is not likely to lead to a significant effect.

INTERACTIONS WITH OTHER MEDICAMENTS
Not applicable.

PREGNANCY AND LACTATION
Pregnancy and breast-feeding
Pregnancy

Animal studies do not indicate any teratogenic effect.
There are no available data on carbocisteine use in pregnant women.
The use of carbocisteine in pregnant women is therefore not recommended.

Breast-feeding
There are no available data on the presence of carbocisteine in human milk.

The use of carbocisteine in breast-feeding women is therefore not recommended.

Effects on ability to drive and use machines
Not applicable.

SIDE EFFECTS
Risk of severe bronchial congestion in infants (see sections Contraindication and **Special warnings and precautions for use**)
- Epigastric discomfort.
- Gastrointestinal disorders (gastric pain, nausea, vomiting, and diarrhea). If these occur, the dose should be reduced.
- Gastrointestinal bleeding. Treatment should be discontinued.
- Allergic skin eruption and anaphylactic reactions such as pruritus, erythematous rash, urticaria and angioedema.
- Fixed rash of drug origin.
- Some cases of fixed drug eruption have been reported.

- Immune system disorders: Anaphylactic / Anaphylactoid reaction
- Skin and Subcutaneous Tissue Disorders: Severe cutaneous adverse reactions (SCAR):
  e.g erythema multiforme, (Stevens-Johnson syndrome – SJS) and toxic epidermal necrolysis (TEN). In most of these cases reported at least one other drug was administered at the same time, which may have possibly enhanced the described mucocutaneous effects.

OVERDOSE
Not applicable.

PHARMACEUTICAL PARTICULARS
Shelf life: 3 years

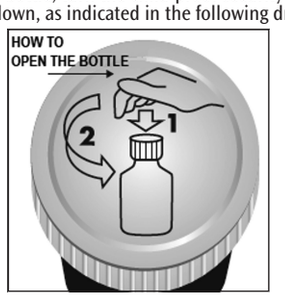
Special precautions for storage
Do not store above 25° C.

Nature and contents of container

Presentations

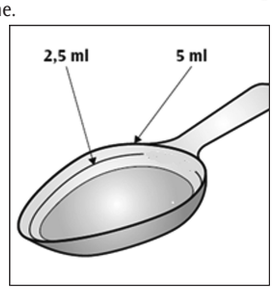
Each box contains a 125 ml bottle and a 5 ml measuring spoon.

Special precautions for disposal and other handling
1. To open the bottle, turn the child-proof security cap while pressing it down, as indicated in the following drawing:



2. This medicine is administered using a measuring spoon for oral administration provided in the carton together with the bottle. The use of this measuring spoon is strictly reserved to oral administration of Rhinathiol expectorant carbocisteine 2% enfants, syrup.

   The total volume of the measuring spoon filled to the brim corresponds to a volume of 5 mL, or a 100 mg dose of carbocisteine.



3. After each use, close the syrup bottle, rinse well the measuring spoon for oral administration with water and dry it, then immediately return the measuring spoon for oral administration in its carton to a place inaccessible for children. Never keep the measuring spoon for oral administration separately from other elements of the medicine package (bottle, carton, package leaflet).

   Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Once the treatment is completed, the medicinal product should be returned
   to a pharmacist (open cartons including the measuring spoon and the bottle) for correct and proper disposal of this medicine.

Manufactured by:
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Opella.