

File information

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Technical colors

Diecut-Legendcase	Free area	Glue points
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Rhinathiol

**5 % adults
EXPECTORANT syrup**

QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine5.00 g

For 100 ml of syrup.

One 15 ml measuring cup contains 750 mg carbocisteine, 6 g sucrose, 203 mg ethanol and 97 mg sodium.

Excipients with known effect: sucrose, sodium, methyl parahydroxybenzoate (E218), ethanol (See section Special warnings and precautions for use)

For the full list of excipients, see section *List of excipients*.

PHARMACEUTICAL FORM

Syrup

CLINICAL PARTICULARS

Therapeutic indications

This medicine is intended in adults (over 15 years of ages) in the event of a recent respiratory disease with expectoration difficulties (difficulty in clearing bronchial secretions via sputum).

Posology and method of administration

Posology

FOR ADULTS ONLY.

- one 15 ml measuring cup contains 750 mg of carbocisteine.
- one 15 ml measuring cup to be taken 3 times daily, preferably without meals.

Duration of treatment

Treatment duration should be short and not exceed 5 days.

Pediatric population

Not applicable.

Method of administration

Oral use.

Contraindications

- Children under 2 years of age.
- Hypersensitivity to the active substance or to any of the excipients (particularly methyl parahydroxybenzoate) listed in section *List of excipients*.
- In case of active gastroduodenal ulcer.

Special warnings and precautions for use

Special warnings

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.

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.

Excipient 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 6 g of sucrose per 15 ml measuring cup. This should be taken into account in patients following low-sugar diets or with diabetes mellitus.

This medicine contains sodium. This medicine contains 97 mg sodium in each 15ml measuring cup. This should be taken into account in patients following a strict low-sodium diet.

This medicine contains methyl parahydroxybenzoate (E218) and may cause allergic reactions (possibly delayed).

This medicine contains 203 mg of ethanol per 15 ml measuring cup of syrup, which is equivalent to 13.53 mg/mL (1.35% w/v). The amount of ethanol in 15 mL of this medicine is equivalent to 4.99 mL of beer or 1.99 mL of wine.

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

Use of this medicinal product is dangerous in alcoholic subjects and use must be considered carefully in pregnant or breast-feeding women and high-risk groups such as patients with hepatic impairment or epilepsy.

Interaction with other medicinal products and other forms of interaction

Combinations to be taken into account

Due to the alcohol content of this medicine:

- **Medicinal products that cause an antabuse-type reaction with alcohol** (hot flushes, redness, vomiting, tachycardia): disulfiram, cefamandole, cefoperazone, latamoxef (cephalosporins, i.e. antibacterial agents), chloramphenicol (phenicol, i.e. antibacterial agent), chlorpropamide, glibenclamide, glipizide, tolbutamide (sulfonylureas, i.e. antidiabetic agents), griseofulvin (antifungal agent), 5-nitroimidazoles (metronidazole, ornidazole, secnidazole, tinidazole), ketoconazole, procarbazine (cytostatic agents).

Central nervous system depressants.

Fertility, pregnancy and lactation

Pregnancy

Animal studies do not indicate any teratogenic effects. 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.

Therefore, the use of carbocisteine in breast-feeding women is not recommended.

Effects on ability to drive and use machines

Not relevant

Undesirable effects

- Epigastric discomfort.
- Possibility of cases of digestive intolerance (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 urticaria, angioedema, pruritus and erythematous rash.
- Fixed rash of drug origin.
- Isolated cases of dermatitis bullous, such as Stevens-Johnson syndrome and erythema multiforme.
- 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.
- Immune system disorders:
Anaphylactic/ anaphylactoid reaction

Overdose

Not applicable.

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 2 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.

PHARMACEUTICAL PARTICULARS

List of excipients

Sucrose, methyl parahydroxybenzoate (E 218), caramel coloring (E 150) (glucose, fructose, dextrose, inverted sugar, sucrose, ammonium hydroxide), cinnamon essential oil, aromatic elixir (contains ethanol) (concentrated rum extract, rum distillate, esters of alcohols: ethyl, propyl, butyl, amyl; acids: acetic, propionic, butyric), sodium hydroxide, purified water.

Incompatibilities

Not applicable.

Shelf-life

Do not use later than the expiry date.

Special precautions for storage

Store below 25°C.

Nature and contents of outer packaging

This medicine is amber coloured syrup with an odour and taste of rum and cinnamon.

Pack in a clear glass bottle containing 125ml with aluminum cap and 15ml measuring cup.

Special precautions for disposal and other handling

No special requirements.

MANUFACTURER:

Unither Liquid Manufacturing

1-3 allée de la NESTE

Z.I. d'En Sigal

31770 Colomiers, France

DATE OF REVISION OF THE TEXT

Feb 2025

(based on FR SmPC Jun 2023)

Opella.