

RHINATHIOL[®] 5% ADULT EXPECTORANT SYRUP

Carbocisteine (5gm/ 100ml)

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What Rhinathiol is used for

Rhinathiol 5% Adult Expectorant syrup is for use in adults (over 15 years of age), in the event of a recent respiratory disease with difficulty expectorating (difficulty clearing bronchial secretions via sputum).

How Rhinathiol works

Rhinathiol belongs to a group of medicines called mucolytics. It contains an active substance called carbocisteine. Rhinathiol thins bronchial secretions (mucus) and makes them easier to cough up.

Before you use Rhinathiol

- When you must not use it

Do not take Rhinathiol if:

- You are allergic to carbocisteine or any of the other ingredients of this medicine (in particular, methyl parahydroxybenzoate) listed at the end of this leaflet.
- You have a stomach or intestinal ulcer.

Do not give Rhinathiol to children under 15 years of age,

- Before you start to use it

You must not use medicines which suppress cough (cough suppressants) or which dry out bronchial secretions when taking Rhinathiol. This is because Rhinathiol thins secretions, making them easier to cough up. Coughing is a useful mechanism for expectoration.

Talk to your doctor or pharmacist before using Rhinathiol:

- If your bronchial secretions are thick and purulent sputum; or if you have a fever.
- If you suffer from chronic (long-term) bronchial or pulmonary disease.
- If you have a history of gastroduodenal ulcers (affecting the stomach or intestine).
- If you are elderly
- If you are also taking medicines that are likely to cause bleeding in the stomach or intestine, treatment should be stopped. If bleeding occurs in the stomach or intestine, it is recommended that treatment be discontinued.

- Taking other medicines

Tell your doctor or pharmacist if you are taking have recently taken any other medicines, including medicines obtained without a prescription.

Other medicines and RHINATHIOL EXPECTORANT CARBOCISTEINE 5 % ADULT syrup

This medicine contains carbocisteine. Other medicines also contain carbocisteine. Do not combine them so as not to exceed the maximum recommended doses (see Dosage/Method of Administration).

Tell your doctor or pharmacist if you are taking, have recently taken or might

take any other medicines.

RHINATHIOL EXPECTORANT CARBOCISTEINE 5 % ADULT syrup with food, drink and alcohol

Take into account the presence of alcohol.

Combinations to be taken into account due to the alcohol content of this medicinal product:

- Medicines causing an antabuse reaction with alcohol (hot flushes, redness, vomiting, rapid heart rate):
 - Disulfiram (for treatment of chronic alcoholism)
 - Cefamandole, cefoperazone, latamoxef, chloramphenicol, metronidazole, ornidazole, secnidazole, tinidazole (antibiotics)
 - Chlorpropamide, glibenclamide, glipizide, tolbutamide (for treatment of diabetes mellitus)
 - Griseofulvin, ketoconazole (antifungal agents)
 - Procarbazine (for treatment of certain cancers)
- Central nervous system depressants

How to use Rhinathiol

Always take Rhinathiol exactly as the doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This medicine should be taken by mouth.

Rinse the measuring cup carefully after each use. Replace the stopper on the bottle with care after use.

- How much to use

For use in adults (over 15 years of age) only

- 1 measuring cup morning, midday and evening, without food and without exceeding 3 measuring cups per day.
- 1 measuring cup = 15 ml = 750 mg of carbocisteine.

- When to use it

Take Rhinathiol morning, midday and evening, without food.

If you are not sure, speak to your doctor or pharmacist.

- How long to use it

Duration of treatment should be brief. Do not exceed 5 days of treatment without medical advice.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose.

- If you use too much

(overdose) Stop the treatment and contact your doctor or pharmacist immediately.

While you are using it

- Things you must do

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

You must talk to a doctor if you do not feel better or if you feel worse.

- Things you must not do

Do not give this medicine to anyone else, even if they have the same condition.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

- Things to be careful of

Use of this medicine is dangerous in alcoholics, and use must be considered in pregnant or breast-feeding women and high-risk groups such as patients with liver failure or epilepsy.

Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

This medicine contains 6 g of sucrose (sugar) per 15 ml of syrup. This should be taken into account in patients following a low-sugar diet or with diabetes mellitus.

This medicine contains sodium. This medicine contains 97 mg of sodium per 15 ml of syrup. This should be taken into account if you are following a low-sodium diet.

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

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

The small amount of alcohol in this medicine will not have any noticeable effects.

Use of this medicine 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are no available data on carbocisteine use in pregnant women.

If you are pregnant, the use of carbocisteine is not recommended.

This medicine should only be used during pregnancy on your

doctor's advice.

If you discover that you are pregnant during treatment, talk to your doctor. Only your doctor can decide whether it is necessary to continue treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

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

Breast-feeding your child is not recommended if you are taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Side Effects

Like all medicines, Rhinathiol can cause side effects, although not everyone gets them.

- Gastrointestinal disorders, such as stomach pain, nausea, vomiting and diarrhea. If these occur, the dosage should be reduced.
- Epigastric discomfort (pain in the upper abdomen).
- Bleeding in the stomach or intestine. Treatment should be stopped.
- Allergic skin eruption and anaphylactic reactions such as hives, itching, appearance of plaques or spots on the skin, and swelling of the face and/or neck that can lead to difficulty breathing and be life-threatening (angioedema). In this case, you should stop treatment and see your doctor immediately.
- Fixed rash of drug origin (allergic skin reaction that recurs in the same part of the body after exposure to the drug again), causing brown or purplish patches that may leave a color on the skin. In this case, you must consult your doctor immediately.
- Appearance of spots, sometimes with blisters, on the

skin that can also affect the mouth (erythema multiforme), appearance of blisters with detachment of the skin that can spread over the whole body and may be life-threatening (Stevens-Johnson syndrome).

If you notice any side effects not listed in this leaflet, or if you some side effects become serious, tell your doctor or pharmacist.

Rhinathiol may cause severe allergy and serious skin reactions. Stop using Rhinathiol and seek medical assistance immediately if you experience any of the following symptoms:

- Severe allergy: breathing difficulties, light headedness, skin swellings or rash.
- Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

Storage and disposal of Rhinathiol

- Storage

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the box. Do not store above 25°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Amber coloured syrup with an odour and taste of rum and

cinnamon.
It is available in 125 ml bottle and comes with a 15 ml measuring cup.

- Ingredients

- Active ingredient
1 measuring cup (15 ml) contains 750 mg of carbocisteine.

- Inactive ingredients
Sucrose, methyl parahydroxybenzoate (E218), caramel coloring (E150), cinnamon essential oil, aromatic elixir (contain alcohol), sodium hydroxide, purified water.

- MAL Numbers

Rhinathiol 5% Adult
Expectorant Syrup
MAL19910983XC

Manufacturer

Unither Liquid
Manufacturing 1-3 allée
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31770 Colomiers, France.

Product Registration Holder

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