

5% Carbocisteine

Rhinathiol

Adult Syrup



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

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1. WHAT RHINATHIOL 5% Adult Expectorant Syrup IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: MUCOLYTICS; ATC Code: R05CB03. (R: Respiratory system)

This medicine is intended for use in adults (aged over 15 years) who have had a recent respiratory disorder with difficulty expectorating (i.e. difficulty coughing up phlegm).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RHINATHIOL 5% Adult Expectorant Syrup

Do not take RHINATHIOL 5% Adult Expectorant Syrup

- if you are allergic to carbocisteine or any of the other ingredients of this medicine (in particular, methyl parahydroxybenzoate) listed in section 6.
- if you have a stomach or intestinal ulcer.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking RHINATHIOL 5% Adult Expectorant Syrup:

A medical opinion is necessary:

- in the event of thick and purulent sputum or 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.

KEEP OUT OF REACH OF CHILDREN.

WARNING: THE ALCOHOL CONTENT OF THIS MEDICINE IS 1.64° OR 0.2 GRAMS OF ALCOHOL PER 15 mL MEASURING CUP, equivalent to 4.92 mL beer or 2.05 mL wine per 15 mL dose.

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.

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

Precautions for use

This medicine should always be accompanied by voluntary coughing attempts, allowing expectoration.

Do not take antitussive medicines (used to calm coughing) or medicines that dry up bronchial secretions during the period of treatment with carbocisteine.

This medicine contains 6 g 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 sodium in each 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.

YOU MUST TALK TO A DOCTOR IF YOU DO NOT FEEL BETTER.

Other medicines and RHINATHIOL 5% Adult Expectorant Syrup

This medicine contains carbocisteine, as do some other medicines. Do not take them together, so that you do not exceed the recommended maximum 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 5% Adult Expectorant Syrup with food, drink and alcohol

Take into account the presence of alcohol.

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.

RHINATHIOL 5% Adult Expectorant Syrup contains sucrose, sodium, methyl parahydroxybenzoate (E218) and ethanol (alcohol).

3. HOW TO TAKE RHINATHIOL 5% Adult Expectorant Syrup

Do not use this medicine in children under 15 years of age.

Dosage

FOR USE IN ADULTS ONLY (over 15 years of age).

- one measuring cup in the morning, at midday and in the evening, without food and without exceeding

- 3 measuring cups per day.
- one 15 ml measuring cup contains 750 mg of carbocisteine.

THIS MEDICINE WAS PRESCRIBED TO YOU PERSONALLY FOR A SPECIFIC SITUATION:

- IT MAY NOT BE SUITABLE FOR OTHER SITUATIONS.
- DO NOT RECOMMEND ITS USE TO ANOTHER PERSON.

Method of administration

Oral use.

Rinse the measuring cup thoroughly after each use.

Close the bottle tightly after use.

Duration of treatment

The duration of treatment should be brief.

Do not exceed 5 days of treatment without medical advice.

If you take more RHINATHIOL 5% Adult Expectorant Syrup than you should:
STOP TREATMENT AND CONSULT YOUR DOCTOR IMMEDIATELY.

If you forget to take Rhinathiol 5% Adult Expectorant SYRUP:
Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Gastrointestinal disorders, such as stomach pain, nausea, vomiting and diarrhea. If these occur, the dosage should be reduced.
- 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.
- Brown or purple plaques which can cause skin discoloration (fixed drug eruption). In this case, you should see 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE RHINATHIOL 5% Adult Expectorant Syrup

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 packaging. The expiry date refers to the last day of that month.

Store below 25° C.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RHINATHIOL 5% Adult Expectorant Syrup contains

The active substance is:

Carbocisteine. 5 g
for 100ml of syrup.

The other ingredients are: sucrose, methyl parahydroxybenzoate (E218), caramel coloring (E150), cinnamon oil, aromatic elixir, sodium hydroxide, purified water.
Alcohol content (v/v): 1.64°.

One measuring cup (15 ml) contains 750 mg carbocisteine, 6 g sucrose, 0.2 g ethanol and 97 mg sodium.

What RHINATHIOL 5% Adult Expectorant Syrup looks like and contents of the pack

This medicine is an amber coloured syrup with an odour and taste of rum and cinnamon. 125 ml bottle with a 15 ml measuring cup.

Manufacturer

UNITHER LIQUID MANUFACTURING
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Z.I. d'en Sigal
31770 Colomiers - France

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