

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.
- Keep out of the reach of children.

What is in this leaflet

1. WHAT RHINATHIOL 2% CHILDREN SYRUP IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RHINATHIOL 2% CHILDREN SYRUP
3. HOW TO TAKE RHINATHIOL 2% CHILDREN SYRUP
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE RHINATHIOL 2% CHILDREN SYRUP
6. CONTENTS OF THE PACK AND OTHER INFORMATION.

1. WHAT RHINATHIOL 2% CHILDREN SYRUP IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: MUCOLYTIC - ATC code: R05CB03 (R: Respiratory system)

This medicine is used to make phlegm more fluid, thus making it easier to cough up.

It is intended for use in patients with congestion of lung airways.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RHINATHIOL 2% CHILDREN SYRUP

Do not take Rhinathiol 2% Children Syrup:

- If you (or your child) are allergic to carbocisteine or any of the other ingredients of this medicine (particularly methyl parahydroxybenzoate), listed in section 6.
- if you (or your child) have a stomach or intestinal ulcer.
- If your child is under 2 years of age, as bronchial congestion may become worse.

Warnings and precautions

You (or your child) must not use medicines which suppress coughing (cough suppressants) or which dry out bronchial secretions when taking Rhinathiol 2% Children Syrup. This is because Rhinathiol 2% Children Syrup thins secretions, making them easier to cough up. Coughing is a useful mechanism for expectoration.

Talk to your doctor or pharmacist before taking Rhinathiol 2% Children Syrup:

- If you (or your child) have a fever or are coughing up "greenish" mucus.
- If you (or your child) suffer from chronic (long term) bronchial or pulmonary disease.
- If you (or your child) 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 in the stomach or intestine occurs.

Other medicines and Rhinathiol 2% Children Syrup

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

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.

Breastfeeding

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 2% Children Syrup contains sodium, methyl parahydroxybenzoate (E218), cochineal red A (E124) and sucrose:

- This medicine contains 13 mg sodium in each measuring spoon (5 ml). This should be taken into account if you are following a no-sodium or low-sodium diet.
- This medicine contains methyl parahydroxybenzoate (E218) and cochineal red A (E124). It may cause allergic reactions.
- This medicine contains sucrose:
 - Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
 - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
 - Each measuring spoon contains 3.5 g sucrose. This should be taken into account if you are following a no-sugar or low-sugar diet.

3. HOW TO TAKE RHINATHIOL 2% CHILDREN SYRUP

A 5 ml measuring spoon is supplied with this medicine. You can also use a teaspoon.

Dosage for children aged 2 to 5 years:

The usual dose is one 5 ml measuring spoon twice a day (i.e. 200 mg per day, divided into 2 doses).

Dosage for children aged over 5 years:

The usual dose is one 5 ml measuring spoon three times a day (i.e. 300 mg per day, divided into 3 doses).

Method of administration

This medicine should be taken by mouth.

Use the measuring spoon provided to measure the quantity of syrup for one dose (5 ml).

Rinse the measuring spoon thoroughly after each use.

Close the bottle tightly after use.

Duration of treatment

Do not use for more than 8 to 10 days. Talk to your doctor if symptoms worsen or persist after 10 days of treatment.

If you take more Rhinathiol 2% Children Syrup than you should

Stop the treatment and contact your doctor or pharmacist immediately.

If you forget to take Rhinathiol 2% Children 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.

- Possible worsening of bronchial congestion in infants.
- 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).

5. HOW TO STORE RHINATHIOL 2% CHILDREN 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.

Do not store above 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 2% Children Syrup contains

The active substance is:

Carbocisteine 2 g for 100 ml of syrup.

The other ingredients are: sucrose, methyl parahydroxybenzoate (E218), vanillin, cochineal red A (E124), raspberry flavor, cherry flavor, sodium hydroxide, purified water.

What Rhinathiol 2% Children Syrup looks like and contents of the pack

This medicine is a red syrup with raspberry and cherry flavour.

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

Manufacturer

UNITHER LIQUID MANUFACTURING

1-3, allée de la Neste, ZI d'en Sigal 31770 Colomiers

- France

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