

RHINATHIOL® 2% CHILDREN SYRUP

Carbocisteine (2gm/ 100ml)

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What Rhinathiol is used for

Rhinathiol thins bronchial secretions (mucus) and makes them easier to cough up (expectorate).

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 (or your child) are allergic to carbocisteine or any of the other ingredients of this medicine (particularly methyl parahydroxybenzoate), listed at the end of this leaflet.
- You (or your child) have a stomach or intestinal ulcer
- Your child is under 2 years of age, as bronchial congestion may become worse.

- Before you start to use it

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 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 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.

- Taking other medicines

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.

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.

Use this measuring spoon for oral administration to measure the dose of carbocisteine to be taken. The total volume of the measuring spoon filled to the brim corresponds to a 100 mg dose of carbocisteine (that is, a volume of 5 mL).

Rinse the measuring spoon thoroughly after each use. Close the bottle tightly after use.

- How much to use

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).

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).

- When to use it

Give Rhinathiol at about the same time each day to your child unless your doctor tells you otherwise.

- How long to use it

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 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

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® 2% CHILDREN SYRUP contains sodium, methyl parahydroxybenzoate (E218), cochineal red A (E124), sucrose and alcohol:

- This medicine contains 13 mg of 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). These can 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 of sucrose. This should be taken into account if you are on a no-sugar or low-sugar diet.
- This medicine contains 31 mg of alcohol (ethanol) per 5 mL measuring spoon of syrup, which is equivalent to 6.2 mg/mL (0.62% w/v). The amount of alcohol 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 medicine will not have any noticeable effects.

Side Effect

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

- 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).

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)).

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47301 Petaling Jaya
Selangor Darul Ehsan, Malaysia

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

Red syrupy liquid with an odour of raspberry and cherry. It is available in 125ml bottle and comes with a 5ml measuring spoon.

- Ingredients

- Active ingredient

One 5 ml measuring spoon contains 100 mg of carbocisteine.

- Inactive ingredients

Sucrose, methyl parahydroxybenzoate (E218), vanillin, cochineal red A (E124), raspberry flavoring, cherry flavoring, sodium hydroxide, purified water

- MAL Numbers

Rhinathiol 2%
Children Syrup
MAL19910914XC

Manufacturer

Unither Liquid
Manufacturing 1-3
allée de la NESTE
Z.I. d'En Sigal
31770 Colomiers, France.

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent,
Paradigm, No. 1, Jalan

Date of revision

10/09/2024 (based on FR PIL Jun23)

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