

RHINATHIOL PROMETHAZINE[®] SYRUP

Carbocisteine / Promethazine Hydrochloride (100mg / 2.5mg per 5ml)

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What Rhinathiol Promethazine is used for

Rhinathiol Promethazine is used for symptomatic treatment of troublesome and non-productive cough, particularly occurring at night.

How Rhinathiol Promethazine works

Rhinathiol Promethazine syrup contains a combination of two active ingredients, carbocisteine (mucolytics) and promethazine hydrochloride (phenothiazines).

Carbocisteine works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

Phenothiazine works by blocking the effects of a certain natural substance (histamine), which causes allergy symptoms. It also has sedating effects which is useful in people with disturbing sleep.

Before you use Rhinathiol Promethazine

-When you must not use it

Do not take Rhinathiol Promethazine if:

- You are allergic (hypersensitive) to carbocisteine or any of the other ingredients of Rhinathiol particularly methyl paraben and other paraben salts (listed in Section Ingredients).
- Signs of allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Your child is under 2 years of age.

Due to the presence of promethazine hydrochloride:

- You are allergic (hypersensitive) to promethazine (or antihistamine)
- You have had low numbers of white blood cells (agranulocytosis) in the past
- You have the risk of developing urine retention due to prostate or urethral disorders
- You have the risk of developing increased pressure in the eye (angle-closure glaucoma)

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Rhinathiol Promethazine.

-Before you start to use it

Check with your doctor before taking Rhinathiol Promethazine if:

Related to Carbocisteine

- You have ulcers in your stomach or gut.

Related to Promethazine

- You have fits (epilepsy)
- You are an elderly with
 - long term constipation problem or
 - benign enlargement of prostate or
 - feeling dizzy or faint when you stand or sit up quickly (postural hypotension), sedation.
- You have fast heartbeat (tachycardia) and low blood pressure.
- You have severe liver and /or kidney insufficiency.
- Your child has asthma or digestive problems where stomach contents, including acid, can travel backward up esophagus.

Related to ingredients

- You have diabetes
- You are following a low-carbohydrate or low-salt diet.
- You have rare genetic problems such as sugar intolerance, malabsorption and sugar enzyme deficiency.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Rhinathiol Promethazine.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or

might take any other medicines as these **combinations are inadvisable:**

- Alcohol
- Sultopride-used to treat schizophrenia

Combinations could be taken into consideration:

- Other central nervous system depressants (sedative antidepressants, barbiturates, clonidine and related substances, hypnotics, morphine derivatives (painkiller and antitussives), methadone, neuroleptics, anxiolytics)
- Atropine and other atropine substances (imipramine antidepressants, anticholinergic antiparkinsonians, atropine antispasmodics, disopyramide, phenothiazine neuroleptics)
- Addition of adverse atropine effects such as urine retention, constipation, dry mouth.

Do not take an antitussive medicine (intended to calm coughing) during the period of treatment with Rhinathiol Promethazine.

How to use Rhinathiol Promethazine

Always take Rhinathiol Promethazine exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

- Take this medicine by mouth
- Rhinathiol Promethazine syrup comes with a measuring spoon.

-How much to use

Adults (including the elderly)

- Usual dose is 3 to 4 table-spoonfuls (1 tablespoon = 15ml) per day, in divided doses.

Children: use the measuring spoon supplied with this syrup:

- 25 to 30 months: Usual dose is 3 to 4 of the 5ml measuring-spoonfuls per day, in divided doses.
- 30 months to 12 years: 4 to 6 of the 5ml measuring-spoonfuls per day, in divided doses.
- 12 to 15 years: 6 to 9 of the 5ml measuring-spoonfuls per day, in divided doses.

Rhinathiol Promethazine is not recommended for use in children below 2 years of age due to fatal breathing difficulty.

For children 2 to 6 years of age to be used with caution and on doctor's or pharmacist's advice.

-When to use it

Take Rhinathiol Promethazine at about the same time each day unless your doctor tells you otherwise.

This medicine should preferably be taken in the evening, because of the sedative effect of promethazine.

-How long to use it

Treatment should be for a short period of time (few days) and restricted when cough occurs.

-If you forget to use it

-If you forget a dose, do not worry. Just wait until the next dose is due. Do not take a double dose to make up for a forgotten dose.

- If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

If you take more Rhinathiol Promethazine syrup than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: seizures (fits- especially in children), impaired consciousness and coma.

While you are using it

-Things you must do

-Talk to your doctor before taking this medicine **if you are pregnant, might become pregnant, or think you may be pregnant.** Rhinathiol Promethazine should be avoided during first trimester of pregnancy, and should only be prescribed thereafter if necessary. It is also limited to occasional use in the 3rd trimester.

If this medicine is used at the end of pregnancy, monitoring of nerves and digestive function in the newborn appears to be warranted.

-You should not take this medicine **if you are breast-feeding.** This is because small amounts may pass into mothers' milk. This can be harmful to your baby.

-Phenothiazine can make your skin more sensitive to sunlight. **Keep out of direct sunlight while taking this medicine.**

-Things you must not do

- Do not give this medicine to anyone

else, even if they have the same condition as you.

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

- Do not stop taking Rhinathiol Promethazine, or change the dosage, without checking with your doctor.

- Do not consume alcoholic beverages or alcohol-containing medicinal while taking Rhinathiol Promethazine.

-Things to be careful of

Driving and using machines

You may feel drowsy when taking Rhinathiol Promethazine. This is exacerbated by alcoholic beverages or medicinal products containing alcohol. If this happens to you, do not drive or use any tools or machines.

Side effect

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Side effects related to carbocisteine

- Severe airway congestion, particularly in infants.
- Allergic skin reactions such as itching, skin redness, hives and swelling under the skin
- Possible digestive disorders (gastric pain, nausea, diarrhoea)

Side effects related to Promethazine

-Brain problems

- Sedation or drowsiness, more marked at the beginning of treatment.
- Anticholinergic effects (such as constipation, eye cannot focus, excessive or prolonged dilation of pupil, pounding of heart beat, urine retention)
- Feeling dizzy or faint when you stand or sit up quickly (postural hypotension)
- Balance disorders, dizziness, impaired memory or concentration
- Lack of muscle coordination, feel shaky (more prone to elderly)
- Confusion, hallucination (hear, smell, taste or feel things that do not exist)
- Agitation, nervousness, difficult to sleep

-Skin sensitization problems

- Eczema, itching, nettle rash
- Purplish discolouration on the skin (purpura)
- Asthma attack

- Water retention (edema)
- Severe, potentially life threatening skin reaction (anaphylactic shock)
- Sensitive to light

-Blood problems

- A decrease in white blood cells count, platelets, red blood cells

Other side effects not listed above may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI /Vaccine Safety).

Storage and Disposal of Rhinathiol Promethazine

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

-Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Rhinathiol Promethazine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Amber coloured syrupy liquid with a cocoa and vanilla odour. They are available in 125ml bottle and come with a measuring spoon.

-Ingredients:

-Active ingredients
promethazine hydrochloride
carbocisteine

-Inactive ingredients

Sucrose, methyl paraben (E 218), powdered caramel colorant (E150), cocoa flavoring, vanillin, ethanol, sodium hydroxide and purified water.

-MAL Numbers:

MAL19860278AZ

Manufacturer

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

Product Registration Holder

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