

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Keep out of the reach of children.

What is in this leaflet

1. What Rhinathiol Promethazine Syrup is and what it is used for
2. What you need to know before you take Rhinathiol Promethazine Syrup
3. How to take Rhinathiol Promethazine Syrup
4. Possible side effects
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1. What Rhinathiol Promethazine Syrup is and what it is used for

This drug contains promethazine (an antihistamine) and carbocisteine.

It is recommended for the alleviation of unproductive and irritative coughs in adults and children aged 2 years and above, particularly when coughing occurs at night.

2. What you need to know before you take Rhinathiol Promethazine Syrup

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Do not take Rhinathiol Promethazine Syrup

- infants (under 2 years of age) due to the risk of worsening of bronchial congestion
- if you are allergic to any of the active substances (promethazine, carbocisteine) or any of the other ingredients of this medicine listed in section 6
- if you have previously or recently experienced agranulocytosis (a major drop in the number of white blood cells in the blood)
- if you have difficulty urinating due to prostate or other problems
- if you are at risk of certain types of glaucoma (increased pressure inside the eye)
- if you are breast-feeding

This medicine **MUST NOT BE USED** during pregnancy.

CHECK WITH YOUR DOCTOR OR PHARMACIST IF YOU ARE NOT SURE.

Warnings and precautions

Take special care with Rhinathiol Promethazine Syrup:

NOTE: THIS MEDICINE CONTAINS ALCOHOL

The alcoholic content of the syrup is 3.09%, i.e.:

- 122 mg of alcohol per measuring-spoon (5 ml)
- 366 mg of alcohol per tablespoon (15 ml)

This medicine must not be used in infants aged under 2 years because of the risk of serious respiratory disorders related to the promethazine content.

Furthermore, this medicine should not be used in children under 2 years of age where phenothiazines such as promethazine are considered to be a potential risk factor for sudden infant death syndrome.

The onset of cough in infants requires consultation with a doctor.

Cough is a symptom which can have different causes: respiratory infection, bronchitis, influenza, allergy, asthma, whooping cough, irritation, etc. Furthermore, tobacco use causes coughing to worsen or persist. There are two types of cough: dry cough and productive cough (increased bronchial secretions). You should not use this medicine to treat a productive cough. Productive cough is a natural defence mechanism which is necessary in order to expel bronchial secretions (mucus).

If a productive cough develops, with congestion, sputum or fever, ask your doctor for advice.

Do not attempt to treat a productive cough by using a syrup for productive cough at the same time as this medicine.

Do not continue treatment with this medicine if symptoms worsen.

In this case, consult your doctor for a re-evaluation of your treatment.

Due to the photosensitising effect of promethazine (excessive reaction of the skin to ultraviolet (UV) rays and the sun), it is preferable not to expose yourself to the sun or ultraviolet (UV) rays during treatment.

The promethazine in this medicine has neuroleptic activity.

Due to the anticholinergic properties of promethazine, the risk of severe constipation or even enterocolitis is increased when combined with other anticholinergic or neuroleptic medicinal products.

Talk to your doctor before taking Rhinathiol Promethazine syrup:

If you have chronic bronchial or pulmonary disease involving coughing and production of sputum.

If you have chronic liver disease (severe liver failure) or kidney disease (severe kidney failure). Your doctor should adapt the dose to your condition.

This medicine should be used with caution:

- in patients with epilepsy due to the possibility of lowering the seizure threshold
- in patients with heart disease, due to the risk of increased heart rate (tachycardia) and the risk of a drop in blood pressure (hypotension)
- in patients with severe kidney or liver disease (kidney or liver failure) due to the risk of accumulation of the medicine in the body
- when using other CNS depressants
- in the elderly if they are predisposed:
 - to constipation
 - to the risk of orthostatic hypotension
 - to dizziness or drowsiness
 - to prostate problems

This medicinal product is not recommended for people 75 years of age and older.

- in case of asthma or gastroesophageal reflux
- if you have a gastroduodenal ulcer (affecting the stomach or intestine)

- during co-administration with medicines liable to cause bleeding in the stomach or intestine. Treatment should be stopped if bleeding in the stomach or intestine occurs.

This medicine should be used with caution due to the risk of sedation. Combination with other sedative medicinal products is not recommended (see section “Taking or using other medicines”)

If you experience fever with or without signs of infection (sore throat), pallor or sweating during treatment, promptly see a doctor.

Other medicines and Rhinathiol Promethazine Syrup

TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU SHOULD ALWAYS INFORM YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER TREATMENT YOU ARE TAKING.

This medicine contains an antihistamine, promethazine, and carbocisteine. Other medicines also contain these substances. Do not co-administer these products, so as not to exceed the maximum recommended dose (see section 3 "How to take Rhinathiol Promethazine Syrup").

You must avoid taking medicines containing alcohol during treatment.

Co-administration with other sedative medicines is not recommended because of the risk of increasing the sedative effect of this medicine.

Taking this medicine during treatment with sodium oxybate (a medicine used in the treatment of narcolepsy) should be avoided.

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

Rhinathiol Promethazine Syrup with food and drink

You should avoid drinking alcoholic beverages and taking medicines containing alcohol during treatment.

Pregnancy and breast-feeding

Pregnancy

This medicine should not generally be used during pregnancy.

If you discover that you are pregnant during treatment, talk to your doctor as soon as possible. Only your doctor will be able to adapt your treatment to your condition. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

The promethazine in this medicine most likely passes into breast milk. Due to its sedative properties which could affect your child (lethargy, loss of energy) or on the contrary stimulating properties (insomnia), this medicine is contraindicated during breast-feeding.

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

Driving and using machines

Attention is drawn especially for those who drive or use machines, to the risk of drowsiness, related to the use of this medicinal product, especially at the start of treatment.

This effect is increased by the consumption of alcoholic beverages or medicinal products containing alcohol.

Contents of Rhinathiol Promethazine Syrup

This medicinal product contains sucrose, consisting of glucose and fructose. It is therefore not recommended for use in patients with fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase insufficiency (rare hereditary diseases).

This medicinal product contains 3 g of sucrose per 5 ml measuring spoon and 9 g per tablespoon. This should be taken into account in patients on a low-sugar diet or with diabetes mellitus.

This medicinal product contains 3.09% V/V ethanol (alcohol), i.e., up to 366 mg per tablespoon of syrup or 1.46 g of ethanol per maximum daily dose (60 ml), which is equivalent to a daily maximum of 37 ml of beer or 15 ml of wine. Use of this medicinal product is dangerous in alcoholics. In pregnant or breast-feeding women, children and high-risk populations such as patients with liver failure or epilepsy, the alcohol content must be taken into account.

This medicinal product contains parahydroxybenzoate and can cause allergic reactions.

This medicinal product contains 13 mg of sodium per 5 ml of syrup. This should be taken into account if patients are on a controlled sodium diet.

3. How to take Rhinathiol Promethazine Syrup

Dosage and administration

This drug is contra-indicated in children less than two years of age. It should be used with caution in children 2 years and above.

Dosage:

For adults and children aged over 2 years only.

Adults

15 ml three to four times a day.

Children

2-5 years of age: 2.5 ml to 5 ml four times a day.

6-12 years of age: 7.5 ml to 12.5 ml three times a day.

12-15 years of age: 12.5 ml to 15 ml three times a day.

Mode or route of administration: oral route.

If an infant develops a cough, consult your doctor.

Wash the measuring-spoon after each use.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR'S OR PHARMACIST'S ADVICE. THIS DRUG HAS BEEN PRESCRIBED FOR YOU PERSONALLY IN A SPECIFIC SITUATION: IT MAY NOT BE SUITABLE FOR OTHER CASES. DO NOT ADVISE ANYONE ELSE TO TAKE IT.

Treatment must be short (a few days) and only at times when coughing occurs.

If you take more Rhinathiol Promethazine Syrup than you should

Contact your doctor or the emergency services immediately. Rhinathiol Promethazine overdose may cause seizures (especially in children), impaired alertness and coma.

If you forget to take Rhinathiol Promethazine Syrup

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

4. Possible side effects

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

- Risk of worsening of bronchial congestion, especially in infants and certain patients unable to cough up sputum effectively.
- Stomach pain, nausea, vomiting, diarrhea. If these occur, the dose should be reduced.
- Bleeding in the stomach or intestine. Treatment should be stopped.

Stop the treatment and contact your doctor immediately:

- Allergic reactions:
 - o Skin rash (erythema, eczema, purpura, hives, itching)
 - o asthma attack
 - o Quincke's oedema (sudden swelling of the face and neck that can lead to difficulty breathing)
 - o anaphylactic shock
- Photosensitisation: excessive skin reaction after exposure to the sun or ultraviolet (UV) radiation
- Respiratory depression
- Major drop in white blood cells in the blood may manifest itself by the appearance or occurrence of a fever whether or not accompanied by signs of infection
- Abnormal reduction of platelet count in the blood may be shown by nosebleeds or bleeding gums
- Fixed pigmented erythema (brown skin patch)
- 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). Stop the treatment and consult a doctor.

The following effects can occur more frequently:

- drowsiness, reduced alertness, particularly at the start of treatment
- memory or concentration disorders, dizziness (especially in the elderly)
- motor incoordination (difficulty in coordinating movements), tremors, abnormal movements
- compelling urge to move (akathisia)
- confusion, hallucinations
- dry mouth, visual disturbances, urinary retention (difficulty passing urine)
- constipation, bowel obstruction, slowing of bowel movement with the possibility of serious bowel damage (ischemic colitis)
- palpitations, drop in blood pressure, major drop in blood pressure upon standing up which sometimes causes dizziness and/or malaise (postural hypotension)

More rarely: agitation, nervousness, insomnia.

5. How to store Rhinathiol Promethazine Syrup

Keep this medicine out of the sight and reach of children.

Do not use Rhinathiol Promethazine Syrup after the expiry date which is stated on the bottle.

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**Contents of Rhinathiol Promethazine Syrup****The active substance is:**

Carbocisteine	2.00 g
Promethazine hydrochloride	0.05 g
For 100 ml of syrup.	

The other ingredients are: Excipients: sucrose, methyl parahydroxybenzoate (E 218), powdered caramel colorant (E 150), cocoa flavoring, vanillin, alcohol, sodium hydroxide, purified water.

One measuring spoon (5 ml) contains: 100 mg of carbocisteine, 2.5 mg of promethazine hydrochloride, 3 g of sucrose and 122 mg of alcohol.

What Rhinathiol Promethazine Syrup looks like and contents of the pack

This medicine is a syrup.

Each pack contains a 125 ml bottle.

Name and address of manufacturer

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

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