

PROMETHIOL SYRUP

Carbocisteine 20mg/ml, Promethazine Hydrochloride 0.5mg/ml

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What Promethiol Syrup is used for

Promethiol Syrup is used for symptomatic treatment of troublesome, non-productive cough, particularly occurring at night.

How Promethiol Syrup works

Promethazine is a sedating antihistamine. It blocks the effects of the naturally occurring chemical histamine in the body. It provides a drying effect on the nasal and oral mucosa. It is commonly used in the preparation for symptomatic treatment of coughs and the common cold.

Carbocisteine is used to dissolve or breakdown mucus in respiratory disorders associated with productive cough.

Before you use Promethiol Syrup

- When you must not use it

This medicines is contraindicated in the following cases:

1. History of hypersensitivity to one of the components (particularly to promethazine HCl, carbocisteine, to any other phenothiazine medications or parabens)
2. Infants under two years of age
3. Because of the presence of promethazine hydrochloride:
 - Hypersensitivity to antihistamines,
 - History of agranulocytosis,
 - Risk of urine retention related to urethral or prostate disorders,
 - Risk of angle-closure glaucoma

Use of this medicine is generally inadvisable in combination with sultopride.

Pregnancy and lactation

Do not take Promethiol Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Promethiol Syrup if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if you are allergic to any medicines or if you have any other medical condition. Inform your doctor if you are pregnant or breastfeeding.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Concurrent use of Promethiol Syrup and the following drugs must be avoided or if necessary, use with care:

- Alcohol
- Other central nervous system depressants (sedatives, antidepressants, barbiturates, clonidine and related substances, hypnotics, morphine derivatives (analgesics and antitussives), methadone, neuroleptics, anxiolytics).
- Atropine and other atropine substances (imipramine, antidepressants, anticholinergic antiparkinsonians, atropine, antispasmodics, disopyramide, phenothiazine neuroleptics)
- Sultopride

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Promethiol Syrup

- How much to use

For oral administration.

Adults

3 to 4 tablespoonfuls (1 tablespoon = 15ml) per day, in divided doses.

Children

- 25 to 30 months:
15 – 20ml per day, in divided doses.

- 30 months to 12 years:
20 – 30ml per day, in divided doses.
- 12 to 15 years:
30 – 45ml per day, in divided doses.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Promethiol Syrup for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much syrups may cause seizures (especially in children), consciousness disorders, coma.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Promethiol Syrup.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Promethiol Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of**Driving and using machines**

Patients who drive or use machines should be warned of the risk of drowsiness associated with this medicinal product, particularly at the start of treatment.

This is exacerbated by alcoholic beverages or medicinal products containing alcohol.

Side effects

Like all medicines, Promethiol Syrup can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Related to the presence of carbocisteine:

- Risk of severe bronchial congestion particularly in infants and in some patients incapable of effective expectoration.
- Allergic skin reactions such as pruritus, erythematous eruption, urticaria and angioedema.
- A few cases of fixed drug eruption have been reported.
- Possibility of gastrointestinal intolerance symptoms (gastric pain, nausea, diarrhea). In this event it is recommended to reduce the dosage.

Related to the presence of promethazine:

The pharmacological characteristics of the substance are responsible for more or less severe adverse effects, which may or may not be related to the dose.

Autonomic nervous system effect:

- Sedation or drowsiness, more marked at the beginning of treatment
- Anticholinergic effects, such as dryness of the mucosae, constipation, accommodation

disorders, mydriasis, cardiac palpitations, risk of urine retention

- Postural hypotension
- Balance disorders, dizziness, impaired memory or concentration
- Lack of motor coordination, tremor (more frequent in the elderly)
- Confusion, hallucinations
- More rarely, excitatory effects, agitation, nervousness, insomnia

Sensitization reactions:

- Erythema, eczema, pruritis, purpura, urticaria, possibly giant urticaria
- Asthma attack
- Edema, more rarely angioedema
- Anaphylactic shock
- Photosensitization

Hematological effects:

- Leucopenia, neutropenia, exceptional cases of agranulocytosis
- Thrombocytopenia
- Hemolytic anemia

Promethiol Syrup may cause severe allergy and serious skin reactions. Stop using Promethiol Syrup 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.

Other unwanted side effects not listed may occur. Tell your doctor immediately if you experience any side effects.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Promethiol Syrup**- Storage**

Keep out of the reach and sight of children.

Store at temperature below 30°C.

Protect from light and moisture.

- 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**

A clear, brown colour solution with cherry and vanilla flavour.

- Ingredients**- Active ingredient(s)**

Carbocisteine
Promethazine Hydrochloride

- Inactive ingredient(s)

Sucrose
Methyl Paraben
Propyl Paraben
Glycerine
Citric Acid
Disodium Edetate
Ascorbic Acid
Sodium Metabisulfite
Caramel Powder
Vanilla Powder
Propylene Glycol
Sodium Hydroxide
Cherry Flavor

- MAL number:

MAL17107093AZ

Manufacturer & Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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