

Package leaflet: Information for the patient

Mucotal Promethazine syrup

Carbocisteine 100 mg / 5ml and Promethazine 2.5 mg / 5ml

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.
- 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. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Mucotal Promethazine is and what it is used for
2. What you need to know before you take Mucotal Promethazine
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1. What Mucotal Promethazine is and what it is used for

Mucotal Promethazine contains the active substances carbocisteine and promethazine.

Carbocisteine belongs to a group of medicines called “mucolytics”. It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

Promethazine belongs to a group of medicines called phenothiazines. It works by blocking a natural substance: Histamine. This will suppress or relieve your coughing.

This medicine is recommended for the relief of dry, irritating cough in adults and children over 2 years of age, particularly when occurring in the evening or at night.

2. What you need to know before you take Mucotal Promethazine

Do not take Mucotal Promethazine and talk to your doctor in the following situations:

- History of allergy (hypersensitivity) to carbocisteine, promethazine or any of the other ingredients of this medicine (listed in section 6) particularly to methyl paraben and other paraben salts.
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Infants (under 2 years of age), because of the risk of serious respiratory damage since this medicine contains promethazine, and the risk of worsening airway congestion related to the carbocisteine in the syrup.
- History of or recent agranulocytosis (considerable reduction in the number of white blood cells).
- Difficulty urinating whether related to the prostate or not.
- If you are at risk of narrow-angle glaucoma (increased pressure inside the eye with a possible impact on eyesight).

- If you are taking medicine containing cabergoline or quinagolide (used to reduce excessive prolactin production).

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

Warnings and precautions:

Take special care with Mucotal Promethazine:

- If an infant develops a cough, you must seek medical advice.
- This medicine must not be used in infants aged under 2 years because of the risk of serious respiratory disorders related to the promethazine and carbocisteine content of the syrup.
- If cough persists despite using Mucotal Promethazine, do not increase the doses. Contact your doctor. Cough is a symptom which can have different causes: respiratory infection, bronchitis, influenza, allergy, asthma, whooping cough, irritation, etc.
- This medicine should not be used to treat a productive cough, which is a natural defense mechanism necessary for expelling phlegm (mucus).
- If a productive cough develops, associated with congestion, expectoration and fever, seek medical advice.
- If you or your child suffer from chronic (long-term) bronchial or lung disease, with coughing and expectoration, medical advice is essential.
- Avoid using a medicine that loosens phlegm along with this medicine (i.e an expectorant or mucolytic agent).
- You should avoid exposure to sun and ultraviolet radiation (UVA) during treatment.

Precaution for use:

Talk to your doctor before taking Mucotal Promethazine:

- 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.
- if you have cardiovascular disease.
- If you have epilepsy.
- If you are aged over 65 years (particularly if you experience chronic constipation, difficulty passing urine due to an enlarged prostate, hypotension, dizziness or drowsiness).
- If your child has asthma or gastroesophageal reflux.
- This medicine may cause drowsiness and should be used with caution.
- 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.

During treatment, tell your doctor:

- If you experience fever with or without signs of infection (sore throat, etc.), paleness or sweating.

Childrens and adolescents:

Mucotal Promethazine is intended for adults and children over 2 years old. It must not be given to children less than 2 years old.

Other medicines and Mucotal Promethazine:

Do not take Mucotal Promethazine with medicines containing cabergoline or quinagolide (used to reduce excessive prolactin production).

Avoid taking medicines containing alcohol during treatment.

Numerous medicines (especially sedative drugs) can reduce alertness. Co-administration with Mucotal Promethazine may increase this effect.

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

Mucotal Promethazine with food and drink:

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

Pregnancy and breast-feeding:

If you discover that you are pregnant during the treatment, consult your doctor. He/she will determine whether you should continue treatment during pregnancy.

Abusively using this medicine at the end of pregnancy may have harmful effects on the newborn infant.

Consequently, you should always ask your doctor for advice before taking this medicine and never exceed the recommended dose and treatment duration.

As a precautionary measure, breast-feeding is not recommended for newborns.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines:

This medicine may cause drowsiness, especially at the start of treatment. Driving or using machines is not recommended if you experience this effect.

The risk of drowsiness increases if you drink alcoholic beverages or take medicines containing alcohol.

Important information about some of the ingredients of Mucotal Promethazine:

This medicine contains:

- Sucrose: This medicine contains 5 g of sucrose in each 15ml dose. This should be taken into account in patients with diabetes mellitus. If your doctor has told you that you or your child have an intolerance to some sugars, talk to your doctor before taking this medicine.
- Ethanol: This medicine contains 13.35 % ethanol (alcohol). A 15 ml dose of this medicine contains up to 1580 mg of ethanol; this is about the same amount of alcohol as 40 ml of beer or 16.66 ml of wine per dose. This can be harmful for those suffering from alcoholism. It should also be taken into account in pregnant or breast-feeding women and high risk groups such as patients with liver disease or fits (epilepsy).
- Sodium: This medicine contains 46 mg of sodium in each 15ml dose. Take this into consideration if you are on a controlled sodium diet.
- Methyl parahydroxybenzoate and a colouring agent – FDC Yellow 6: Both of these ingredients may cause allergic reactions (these may not happen straight away). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

3. How to take Mucotal Promethazine

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Taking this medicine:

- Take this medicine by mouth.
- If you feel that this medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
- This medicine is intended for adults and children over 2 years old only.

How much to take:

- For adults: The usual dose is 45-60 ml per day (3 to 4 tablespoonfuls).
- For children:
 - o From 12 to 15 years: The usual dose is 30-45 ml per day (6 to 9 teaspoonfuls).
 - o From 36 months to 12 years: The usual dose is 20-30 ml per day (4 to 6 teaspoonfuls).

- From 24 to 36 months: The usual dose is 15-20 ml per day (3 to 4 teaspoonfuls).
- Treatment should be brief (a few days) and limited to episodes of coughing.

If you take more Mucotal Promethazine than you should

If you take more of this medicine than you should, stop taking it and tell your doctor or go to a hospital straight away. Take this medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Mucotal Promethazine

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

- Risk of worsening airway congestion particularly in infants and in certain patients who have difficulty coughing up phlegm (mucus).
- Possible digestive disorders: stomach pain, nausea, diarrhea. If any of these occurs, you should reduce the dose.
- Bleeding in the stomach or intestine. Treatment should be stopped.
- Allergic skin reactions such as itching, skin rash, hives and swelling of the face.
- Some cases of fixed drug eruption (brownish spots on the skin) have been reported.
- 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).

Some side effects require that you immediately stop treatment and inform your doctor:

- If you have signs of allergy to the medicine such as:
 - redness, itching (pruritus), eczema, purple marks on the skin (purpura),
 - hives
 - edema, sudden swelling of the face and/or neck that can lead to difficulty breathing and be life-threatening (angioedema),
 - asthma attack
 - sudden malaise with a significant decrease in blood pressure (anaphylactic shock).
- If you have an excessive skin reaction after exposure to sun or UV radiation.
- If you have symptoms possibly caused by a decrease in white blood cell, platelet or red blood cell counts. These symptoms can be recognized by:
 - fever, sometimes with infection (caused by a major drop in white blood cell count),
 - nosebleed or bleeding gums (caused by an abnormal reduction in platelet count).

Other effects are more common:

- Drowsiness, impaired alertness, more pronounced at the start of treatment.
- Memory or concentration disorders, dizziness (more common in the elderly).
- Difficulty coordinating movements, tremor.
- Confusion, hallucination.
- Dry mouth, visual disturbances, urinary retention, constipation, palpitations, decrease in blood pressure upon standing up, which sometimes causes dizziness and/or malaise (postural hypotension).

More rarely, signs of excitation such as agitation, nervousness, insomnia may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mucotal Promethazine

- - 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 label and the outer packaging. The expiry date refers to the last day of that month.
- - Do not store above 30°C. Keep away from humidity.
- - Do not refrigerate.
- - Do not use this medicine if you notice any change in the appearance of the oral solution.
- - Do not throw away any medicines via wastewater. 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 Mucotal Promethazine contains

- The active substances are carbocisteine and promethazine hydrochloride. Each 5 ml of syrup (1 teaspoonful) contains 100 mg of carbocisteine and 2.5 mg of promethazine.
- The other ingredients are water, ethanol, propylene glycol, citric acid, sodium saccharine, sodium hydroxide, sodium citrate, sucrose, methylparahydroxybenzoate (or methylparaben), FDC Yellow 6 and caramel flavour.

What Mucotal Promethazine looks like and contents of the pack

Mucotal Promethazine is an Orange syrup caramel flavored.

Mucotal Promethazine is available in 150 ml bottle.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon

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Contact us: pharmaline@maliagroup.com

Website: www.pharmaline.com.lb

Reg. No. for Mucotal Promethazine: 27809/94

This is a medicament:

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers
Union of Arab Pharmacists

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