

Package leaflet: information for the user
Promethazine CF 25 mg, coated tablets
promethazine hydrochloride

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience a lot of discomfort from one of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Promethazine CF 25 mg and what is it used for?

This medicine is used to prevent and treat hypersensitivity reactions based on the release of histamine such as hay fever, non-seasonal allergic rhinitis, hives, and other skin diseases based on a direct allergic reaction (itchy welts, insect bites), drug-induced skin rash, and as an aid in other forms of eczema and asthma due to hypersensitivity.

Promethazine is also used for motion sickness such as sea, air, and car sickness.

Promethazine is a phenothiazine derivative that counteracts the effects of histamine on the body. Histamine is a substance in the body responsible for the development of hypersensitivity symptoms. Promethazine is a medication against allergic reactions caused by histamine, with an individually varying, sometimes strongly sedative effect.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- In case of coma.
- During an acute asthma attack.
- In children under 2 years.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- You have increased intraocular pressure.
- After urination, urine remains in your bladder or you have an enlarged prostate.
- You have liver dysfunction, heart or vascular disorder, high blood pressure, or epilepsy.
- You have severe heart problems.
- Heart disease occurs in your personal medical history or that of your family.
- You have an irregular heartbeat.

Promethazine should be used with caution in acutely ill or dehydrated children or in acute infections due to an increased risk of muscle tone disorders, in symptoms of Reye's syndrome, and in symptoms of another liver disease.

Children

Caution is advised in children between 2 and 6 years because they have a higher chance of certain side effects such as drowsiness and abnormal behavior.

In children, caution is also advised in cases of sleep apnea in the medical history, in the occurrence of sudden infant death syndrome in the family, and in children who are less easily awakened spontaneously than normal.

Are you using any other medicines?

Are you using any other medicines besides Promethazine CF 25 mg, coated tablets, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Simultaneous use of alcohol and other substances that have a depressant effect on the central nervous system, such as barbiturates, sleeping pills, strong painkillers, and sedatives, enhance the depressant effect of promethazine on the central nervous system. Therefore, alcohol consumption should be discouraged.

MAO inhibitors (medicines for persistent depression) can enhance the atropine-like effect (paralytic effect on the part of the nervous system responsible for nerve impulses of, among other things, eyes, head, and spinal cord) of promethazine.

The simultaneous use of substances with an atropine-like effect, such as atropine and tricyclic antidepressants (medicines for depression), enhances the atropine-like effect of promethazine. Promethazine can enhance the blood pressure-lowering effect of some medicines for high blood pressure.

Medicines that can affect your heart rhythm.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

Promethazine can, as far as is known, be used during pregnancy without danger to the fetus, according to the prescription. Use during pregnancy only on the explicit advice of the doctor. High dosages at the end of pregnancy may cause movement disorders in the newborn. If

promethazine is given just before delivery, there is a risk of respiratory depression in the newborn.

Breastfeeding

Use during the breastfeeding period is discouraged because promethazine is excreted in breast milk. Due to the strong sedative effect and the possibility of respiratory depression (reported in children under two years who received promethazine), breastfeeding is discouraged when using promethazine simultaneously.

Driving ability and the use of machines

Promethazine causes drowsiness and its use can lead to reduced reaction and concentration ability. You should take this into account when using promethazine. Participation in traffic and the use of machines is discouraged.

Promethazine CF contains sucrose and methylhydroxybenzoate

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

Methylhydroxybenzoate can cause allergic reactions (possibly delayed).

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Dosage and method of use

Dosage

In case of hypersensitivity symptoms:

Adults: 50 - 150 mg (2 - 6 tablets) per day in divided doses during meals and at bedtime. In some cases, 25 mg (1 tablet) per day may already be sufficient.

For motion sickness (sea, air, and car sickness):

Adults: 25 mg (1 tablet) ½ to 1 hour before the start of the journey, repeat after 8 hours if necessary.

Use in children

For motion sickness (sea, air, and car sickness):

Children from 8 years: 25 mg (1 tablet) ½ to 1 hour before the start of the journey, repeat after 8 hours if necessary.

Method of use

Swallow the tablets whole without chewing with some water or other liquid.

Have you taken too much of this medicine?

Call a doctor in case of overdose.

In case of overdose, the nervous system may become more active or suppressed.

In children, the nervous system often becomes more active first, with symptoms such as excitement, restlessness, problems with movement or speech (ataxia), seeing, feeling, or hearing

things that are not there (hallucinations), increased body temperature, tremors, and convulsions. Sometimes eventually even deep coma and severely low blood pressure.

In adults, overdose often first suppresses the nervous system. Symptoms may include drowsiness to coma, reduced breathing, severely low blood pressure, heart rhythm disturbances, and lowered body temperature.

Other symptoms of overdose may include nausea, vomiting, urinary retention, dilated pupils, dry mouth, dry skin, skin redness ('anticholinergic syndrome').

4. Possible side effects

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

Sometimes (occur in less than 1 in 100 users)

- Vascular disorders: lowered blood pressure (hypotension)

Rare (occur in less than 1 in 1,000 users)

- Blood and lymphatic system disorders: very severe blood disorder (shortage of white blood cells) accompanied by sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis), blood disorder (shortage of white blood cells) accompanied by increased susceptibility to infections (leukopenia), anemia due to excessive breakdown of blood (hemolytic anemia)

Not known (cannot be estimated from the available data)

- Blood and lymphatic system disorders: low platelet count (which can lead to bleeding and bruising)
- Psychiatric disorders: apathy, seeing, feeling, or hearing things that are not there (hallucinations), aggression
- Nervous system disorders: disturbance of the central nervous system (extrapyramidal symptoms (at high doses)), sleep disorder (narcolepsy), drowsiness, impaired reaction ability, concentration weakness, dizziness, muscle weakness, condition with an urge to move the legs ("restless legs"), a severe reaction with fever, stiff muscles, changing blood pressure, and coma (neuroleptic malignant syndrome), restlessness
- Eye disorders: blurred vision, narrowing of the pupils (miosis)
- Cardiac disorders: slowed heart rate (bradycardia, especially with parenteral administration), accelerated heart rate (tachycardia, especially with parenteral administration), abnormal electrical activity of the heart affecting the heart rhythm, including life-threatening arrhythmia
- Vascular disorders: slight transient increase in blood pressure (especially with parenteral administration)
- Gastrointestinal disorders: lack of appetite (anorexia), dry nose and mouth, gastrointestinal disorders
- Hepatobiliary disorders: jaundice
- Skin and subcutaneous tissue disorders: sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema), sensitivity to light or sunlight (photosensitization)

- Renal and urinary disorders: retention of urine in the bladder due to impaired bladder emptying (urinary retention), difficult or painful urination (dysuria)
- General disorders and administration site conditions: fatigue, weakness

Additional side effects that may occur in children

Respiratory depression, sleep apnea, and sudden infant death syndrome have been observed in a number of infants and young children who received a usual dose of promethazine. A relationship with promethazine and the possible mechanism of action has not yet been clarified. Paradoxical stimulation of the central nervous system can occur particularly in children, which may be accompanied by insomnia, nervousness, confusion, accelerated heart rate, tremors, and seizures.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Store below 25 C.

Store in the original packaging to protect from light.

Do not use this medicine after the expiry date. It can be found on the packaging after "Do not use after:" or "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information What substances are in this medicine?

- The active substance in this medicine is promethazine hydrochloride equivalent to 25 mg promethazine per coated tablet.
- The other substances in this medicine are potato starch, mannitol, microcrystalline cellulose, povidone K90, anhydrous colloidal silicon dioxide, talc, magnesium stearate, hypromellose, propylene glycol, sucrose, calcium carbonate, arabic gum, macrogolglycerol ricinoleate, methyl parahydroxybenzoate, patent blue V (E131), titanium dioxide (E171), montanglycol wax.

What does Promethazine CF 25 mg, coated tablets look like and how many are in a package? The tablets are blue, coated, round, have rounded edges (biconvex) and have a diameter of approximately 8 mm.

The tablets are packed in a bottle or in multiples of 10 tablets in blister strips per one or more blister strips packed in a cardboard box.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer
Marketing authorization holder
Centrafarm B.V.
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4814 NE Breda
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Manufacturer
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This leaflet was last approved in February 2025.

More information about this medicine is available on the website of the CBG (www.cbg-meb.nl).