

Promethazine 25 mg/ml, solution for injection

Promethazine hydrochloride

What is Promethazine Eureco-Pharma 25 mg/ml, solution for injection and what is it used for?

This medication is used to prevent and treat symptoms of allergic conditions caused by histamine release. It is particularly suitable for use in Quincke's edema and the treatment of shock due to hypersensitivity. This medication is also used for pre-treatment during general anesthesia. Promethazine is an H1 receptor-blocking antihistamine with sedative and atropine-like properties.

When should you not use this medication or be extra cautious with it?

When should you not use this medication?

- If you are allergic to any of the substances in this medication.
- In case of coma.
- During an acute asthma attack.
- If you are allergic to sulfite: especially asthma patients may react with airway spasms or shock.
- In children under 2 years of age.
- When should you be extra cautious with this medication?
- If you have increased eye pressure.
- If urine remains in your bladder after urinating or if you have an enlarged prostate.
- If you have liver dysfunction, heart or vascular abnormalities, high blood pressure, or epilepsy.

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, symptoms of Reye's syndrome, and symptoms of another liver disease.

With intravenous injections, which should be administered slowly and with caution to prevent leakage of the injection fluid from the blood vessel or inadvertent administration outside a blood vessel with the risk of severe irritation.

If you are hypersensitive to sulfites (Sodium sulfite and Sodium bisulfite).

Promethazine Eureco Pharma 25 mg/ml, solution for injection contains sulfites (Sodium sulfite and Sodium bisulfite), which can cause hypersensitivity reactions in sensitive individuals. These reactions can range from mild to severe and may include respiratory distress, shock, and other symptoms.

Asthmatic attacks can lead to fatal shock. Contact your doctor or pharmacist before using this medication.

Children: Caution is advised for children between 2 and 6 years old, as they have a higher risk of certain side effects, such as drowsiness and abnormal behavior. Additionally, caution should be exercised in children with a medical history of sleep apnea, a family history of sudden infant death syndrome (SIDS), or difficulty waking up spontaneously.

Are you taking any other medications?

If you are taking other medications along with Promethazine Eureco-Pharma 25 mg/ml injection solution, have taken them recently, or plan to take them in the near future, tell your doctor or pharmacist.

Alcohol and other central nervous system depressants such as barbiturates, benzodiazepines, and morphine-like painkillers enhance the effects of promethazine on the brain. Therefore, alcohol use should be discouraged.

The simultaneous use of substances that counteract the effects of acetylcholine in the body, such as atropine and tricyclic antidepressants, enhances this anticholinergic effect. Promethazine can enhance the blood pressure-lowering effect of some blood pressure-lowering medications.

MAO inhibitors can enhance the atropine-like effect of promethazine.

Pregnancy and breastfeeding

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor or pharmacist before using this medication.

Promethazine can be used during pregnancy as prescribed without known danger to the fetus.

High doses of promethazine at the end of pregnancy can cause movement disorders in the newborn. If promethazine is given just before delivery, there is a risk of respiratory depression in the newborn.

Because of its strong sedative effect and the possibility of respiratory depression (reported in children under two years of age who received promethazine), breastfeeding is not recommended during simultaneous use of promethazine.

Driving and using machines

Promethazine causes drowsiness, and its use can lead to reduced reaction and concentration.

Promethazine Eureco-Pharma 25 mg/ml injection solution contains sulfites (sodium sulfite and sodium bisulfite).

In rare cases, it can cause severe hypersensitivity reactions and respiratory problems (bronchospasm).

How to use this medication?

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

Dosage and method of use

Dosage: For allergic conditions: Intramuscular: Adults: 25-50 mg per day, maximum 100 mg per day

Intravenous: Adults: slowly, 25-50 mg per day

For premedication before general anesthesia: Intramuscular: Adults: 25-50 mg

Method of use

Intravenous administration: In general, administration will take place through infusion (for example, physiological saline or glucose solution), which also facilitates the administration of the desired combination. Direct injection into the bloodstream should be administered slowly to prevent sudden drops in blood pressure. Due to a possible reaction of the vascular wall, it is recommended to dilute the contents of the vial somewhat with a few ml of physiological saline solution.

Note: Due to the risk of serious tissue damage, the undiluted solution should be administered slowly, and care should be taken to prevent leakage of the injection fluid from a blood vessel and injection into an artery.

Have you used too much of this medicine?

Call a doctor if you overdose.

In the case of overdose, the nervous system can either work harder or be suppressed. In children, the nervous system often works harder first, with symptoms such as excitement, restlessness, difficulty moving or speaking (ataxia), seeing, feeling or hearing things that are not there (hallucinations), increased body temperature, tremors, and seizures. Sometimes, it can even lead to deep coma and a severe drop in blood pressure.

In adults, an overdose often first suppresses the nervous system. Symptoms include drowsiness leading to coma, reduced breathing, a severe drop in blood pressure, arrhythmias, and a lowered body temperature. Other symptoms of an overdose include nausea, vomiting, urinary retention, enlarged pupils, dry mouth, dry skin, and redness of the skin ("anticholinergic syndrome").

Possible side effects

Like any medicine, this medicine can have side effects, although not everyone experiences them.

Common side effects (affecting less than 1 in 100 users): • Vascular disorders: low blood pressure (hypotension)

Rare side effects (affecting less than 1 in 1,000 users): • Blood and lymphatic system disorders: very serious blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat, and sores in the mouth (agranulocytosis); blood disorder (lack of white blood cells) accompanied by increased susceptibility to infections (leukopenia); anemia due to excessive breakdown of the blood (hemolytic anemia)

Side effects of unknown frequency (cannot be determined with available data):

- Immune system disorders: Promethazine Eureco-Pharma 25 mg/ml, solution for injection contains sulfites (sodium sulfite and sodium bisulfite) which can cause allergic reactions in susceptible individuals. These reactions can range from mild asthma attacks to sometimes fatal shock (severe drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, decreased consciousness) due to sudden severe vasodilation resulting from severe hypersensitivity to certain substances (anaphylactic shock).

- Psychological disorders: apathy

- Nervous system disorders: disruption of the central nervous system (extrapyramidal symptoms (at high doses)), sleep disorder (narcolepsy), drowsiness, impaired reaction time, decreased concentration, dizziness, muscle weakness, condition with urge to move legs ("restless legs")

- Eye disorders: blurred vision, narrowing of the pupils (miosis)

- Cardiovascular disorders: slow heartbeat (bradycardia, especially with parenteral administration), fast heartbeat (tachycardia, especially with parenteral administration)

- Vascular disorders: blood clots in the blood vessels (venous thrombosis) at the injection site, narrowing of the blood vessels (arterial spasms), and local tissue death

(gangrene) after unintentional injection into a blood vessel, mild transient increase in blood pressure (especially with parenteral administration)

- Gastrointestinal disorders: loss of appetite (anorexia), dry nose and mouth, gastrointestinal disorders

- Hepatobiliary disorders: jaundice

- Skin and subcutaneous tissue disorders: sudden accumulation of fluid in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema), hypersensitivity to light or sunlight (photosensitivity)

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

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Additional side effects that may occur in children

Suppression of respiration, breathing cessation during sleep, and sudden infant death syndrome have been reported in some 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.

Contradictory stimulation of the central nervous system can occur especially in children, which may be accompanied by insomnia, nervousness, confusion, accelerated heartbeat, tremors, and convulsions.

How to store this medicine?

Keep out of sight and reach of children.

Store in the original package to protect from light.

Do not use this medicine after the expiry date stated on the packaging. The expiry date refers to the last day of that month.

Do not dispose of medicines in the sink or in the garbage can. Ask your pharmacist how to dispose of medicines that are no longer needed. This way, you help to protect the environment.