PACKAGE LEAFLET: Information for the patient

PROMETAZINE

Sugar-coated tablets – 25 mg

Solution for injection – 50 mg / 2 ml

(Promethazine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. WHAT PROMETAZINE IS AND WHAT IT IS USED FOR

Promethazine is a phenothiazine derivative, which decreases or eliminates the main histamine actions by competing with histamine or reversibly blocking histamine receptors in tissues. Promethazine does not deactivate histamine, and does not prevent its secretion. H_1 receptors are responsible for blood vessel dilation, increase of capillary permeability, itching and, up to an extent, for bronchial and gastrointestinal tract smooth muscle contractions. Promethazine has also antimuscarinic properties, antagonizing effects of adrenaline and serotonin and local anesthetic effects.

Prometazine 25 mg sugar-coated tablets are indicated in:

- temporary relief of rhinorrhea and sneezing associated with flu;
- symptomatic relief of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis;
- relief of symptoms such as pruritus of allergic and non-allergic origin;
- treatment of mild, uncomplicated skin manifestations of urticaria and angioedema;
- alleviation of allergic reactions from blood or plasma transfusions;
- treatment of dermographism;
- ancillary treatment in anaphylactic reactions;
- preoperative and postoperative sedation;
- prevention and management of nausea and vomiting associated with certain types of anaesthesia and surgical procedures;
- adjuvant treatment to analgesics for control of postoperative pain;
- facilitation of sleep;
- prevention and treatment of motion sickness (travelling by automobile, plane, ship).

Prometazine 50 mg / 2 ml solution for injection is indicated:

By intramuscular injection:

- in allergy;
- in preoperative sedation;
- in sedation during labor;

By intravenous injection:

- in allergy
- as an adjuvant agent in anaesthesia and analgesia in order to reduce the dose of pethidine or other narcotic analgesics, especially in several specific surgical procedures (for example: repeated bronchoscopy, surgical ophthalmologic intervention).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROMETAZINE

Do not take Prometazine if:

- you are allergic to promethazine hydrochloride or to any of the excipients of this medicine;
- you are hypersensitive to antihistamines;
- you have angle-closure glaucoma;
- you have stenosing peptic ulcer;
- you have symptomatic prostatic hypertrophy;
- you have asthmatic crises;
- you have pyloroduodenal obstruction;
- you have bladder neck obstruction;
- the patient is comatose;
- you have central nervous system depression caused by use of barbiturates, general anaesthetics, tranquilizers, alcohol, narcotic drugs or narcotic analgesics;
- you have had previous idiosyncrasy with phenothiazines;
- you have jaundice or bone marrow depression;
- the patient is an acutely ill or dehydrated child;
- you have sleep apnea, liver disease, or the patient is a child with Reye's syndrome;
- you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Prometazine if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist.

Take special care with Prometazine

Extrapyramidal symptoms that may appear after intravenous injection may be confused with the symptoms of undiagnosed primary diseases (encephalopathy, Reye's syndrome).

Ask your doctor before you take Prometazine if:

- it will be used in children under 2 years of age, because it is not recommended;
- it will be used in the treatment of uncomplicated vomiting in children; it may be used if vomiting is prolonged and of undefined origin;
- you have a tendency of urinary retention;
- you have bronchial asthma;
- you have increased intraocular pressure;

- you have hyperthyroidism;
- you have cardiovascular disease or hypertension;
- you have ulcer disease;
- you have respiratory impairment;
- you have epilepsy.

Special care is required if it will be used in children or elderly, because they are more susceptible to the adverse effects of this medicine.

Extravasation during intravenous use should be avoided.

Promethazine hydrochloride solution for injection is chemically incompatible with medicines of alkaline pH, which may precipitate the insoluble promethazine base.

Other medicines and Prometazine

Use of other medicines with Prometazine could influence Prometazine's effect or the other medicine's effect.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those without prescription. Inform your doctor that you are taking Prometazine, if any medicines are prescribed to you during treatment, particularly the following:

- antimuscarinics, they may decrease promethazine's effect and there is an increased risk of antimuscarinic side effects;
- barbiturates, there is a risk of neuromuscular excitement and increased risk of hypotension;
- opioid analgesics, may potentiate the sedative effects;
- central nervous system (CNS) depressants such as alcohol, barbiturates, or other sedatives, antihistamines, tranquilizers and promethazine may have additive depressive action on CNS;
- monoamine oxidase inhibitors (MAOIs), they may prolong and intensify antimuscarinic effects; they may cause hypotension and extrapyramidal effects if used concomitantly with promethazine; promethazine should be avoided for 2 weeks after stopping MAOIs;
- tricyclic antidepressants, possible increased antimuscarinic and sedative effects may occur if used concomitantly with antihistamines.

Taking Prometazine with food and drinks

It is recommended that Prometazine be taken before meals and its use with alcohol is not recommended.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning a pregnancy, ask your doctor or pharmacist for advice before taking this medicine. Treatment with Prometazine should be avoided during pregnancy.

If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine. Promethazine may appear in breast milk, thus its use during breastfeeding is not recommended.

Driving and using machines

Promethazine may affect the patient's ability to drive or operate machinery.

Important information about some of the excipients of Prometazine

Prometazine sugar - coated tablets contain lactose and sucrose.

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

Prometazine sugar – coated tablets contain sodium benzoate.

Prometazine solution for injection contains sodium sulphite and metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE PROMETAZINE

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure or you feel that Prometazine's effect is too strong or too weak.

In intravenous use, the solution is diluted 10 times with water for injection, the administration should be slow and the rate of infusion should not exceed 25 mg / minute.

Parenteral dosage forms should be visually inspected before use. Only clear solutions with no particles should be used.

Prometazine dosage is as follows:

Allergic conditions, *adults, by mouth*: 25 mg before retiring; *intramuscular or intravenous dose:* 25 mg, this dose may be repeated within 2 hours if necessary.

Children 2 - 5 years, *by mouth:* 6.25 – 12.5 mg, maximum daily dose 15 mg; 5 - 10 years, 25 mg daily in 1 - 2 divided doses.

Motion sickness **(travelling by automobile, plane, ship, etc.)**, *adults, by mouth:* 25 mg as initial dose 30 - 60 minutes before departure or at bedtime, and if necessary, the dose is repeated after 8 – 12 hours.

Children 2 – 10 years, *by mouth*: 12.5 – 25 mg, in 2 divided doses, at bedtime and the following morning. The dose of the following morning is taken only if necessary.

Nausea and vomiting*, adults, by mouth*: 25 mg. Doses of 12.5 – 25 mg, every 4 -6 hours may be repeated as needed.

Prevention of nausea and vomiting, adults, by mouth: 25 mg, every 4 – 6 hours as needed.

Children over 2 years, by mouth: 0.25 - 0.5 mg/kg or every 4 -6 hours as needed.

Preoperative sedation*,* adults, *by mouth*: 50 mg in the evening before surgical intervention; *intramuscular or intravenous dose:* 25 – 50 mg in the evening before surgical intervention.

Children 2 – 5 years, by mouth: 15 – 20 mg;

Children 5 – 10 years, by mouth: 20 - 25 mg;

Children 5 – 10 years, intramuscular dose: 6.25 – 12.5 mg.

Sedation during labour*, intravenous or intramuscular dose*: 50 mg during the early stage of labour. When labour is established, 25 – 75 mg may be injected with a reduction of the narcotic dose (maximum total dose 100 mg / 24 hours).

If you take more Prometazine than you should

If you take more Prometazine than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on the actions that should be taken.

In adults, overdosage of Prometazine may result in deep sleep and coma and, rarely, seizures and cardiorespiratory symptoms. In children, a paradoxical reaction characterized by hyperexcitability, abnormal movements, nightmares, and respiratory depression may occur. Treatment of promethazine overdosage is similar to that of other phenothiazines. Symptomatic supportive therapy is indicated and general physiologic measures such as maintenance of adequate ventilation should be instituted if necessary.

If you forget to take Prometazine

If you forget to take one or more doses, take the next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Talk to your doctor if you have any of the following side effects:

- drowsiness;
- central nervous system depression;
- dizziness;
- dry mouth and throat;
- movement disorders,
- anxiety and tremor;
- irritability, confusion, insomnia;
- blurred vision, hysteria, spasms;
- tinnitus;
- peripheral neuritis, headache;
- anorexia, or increased appetite and weight gain;
- liver problems that may cause the eyes or skin to become yellow (jaundice);
- nausea, vomiting, diarrhea, constipation;
- frequent urination or urinary retention, sexual disorders;
- exanthema, photosensitivity;
- anaphylactic reactions;

- hemolytic anemia, thrombocytopenia, leucopenia, pancitopenia;
- orthostatic hypotension, palpitations, bradycardia, tachycardia, extrasystoles.

If any of these side effects gets worse or if you get any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE PROMETAZINE

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

Do not use Prometazine after the expiry date which is stated on the package.

Store below 25°C.

Keep in the original packaging protected from light.

6. OTHER INFORMATION

What Prometazine contains

The active substance is Promethazine hydrochloride.

Each sugar-coated tablet contains 25 mg promethazine hydrochloride.

The excipients are: maize starch, lactose monohydrate, gelatin, sodium starch glycolate, magnesium stearate, povidone, sucrose, purified talc, calcium carbonate, titanium dioxide, brilliant blue FCF, indigo carmine, sodium benzoate, shellac, carnauba wax, beeswax white.

Each ampoule 2 ml contains 50 mg promethazine hydrochloride (25 mg / ml) (solution for injection 2.5%).

The excipients are: ascorbic acid, sodium chloride, sodium sulphite, sodium metabisulphite, hydrochloric acid (may be added for pH adjustment), and water for injection.

Contents of the pack

Sugar-coated tablets: carton box with 30 sugar-coated tablets.

Solution for injection: carton box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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