

**PROMETHAZINE
HYDROCHLORIDE
5 mg/ 5 mL Syrup**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PROMETHAZINE

Each 5 mL of PROMETHAZINE syrup contains 5 mg promethazine hydrochloride.

Promethazine is a phenothiazine derivative H₁ receptor blocking agent. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic properties.

PROMETHAZINE hydrochloride is useful for:

- Perennial and seasonal allergic rhinitis: PROMETHAZINE relieves sneezing, rhinorrhea, nasal itch and conjunctivitis
- Vasomotor rhinitis
- Allergic conjunctivitis due to inhalant allergens and foods
- Mild, uncomplicated allergic manifestations of urticaria and angioedema
- Amelioration of allergic reactions to blood or plasma
- Pruritic skin disorders
- Adjunctive therapy in anaphylactic reactions
- Preoperative, postoperative, or obstetric sedation
- Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery and in case of drug-induced vomiting
- Adjunctive therapy to analgesics for control of postoperative pain
- Sedation in both children and adults, as well as relief of apprehension and production of light sleep from which the patient can be easily aroused
- Active and prophylactic treatment of motion sickness
- Antiemetic therapy in postoperative patients
- Symptomatic treatment of nausea and vertigo caused by Ménière's disease and other vestibular disorders

The way to take PROMETHAZINE

Take PROMETHAZINE as directed by your physician.

Dosage is individualized on the basis of the condition under treatment and the response of the patient.

The usual recommended doses are:

Indication	Doses for adults and children older than 10 years	Pediatric dose	
		2 to 5 years	5 to 10 years
Treatment of allergic conditions	25 mg (25 mL) at night increased to 25 mg twice daily if necessary, an alternative dose is 10 to 20 mg (10 to 20 mL) two or three times daily	5 to 15 mg (5 to 15 mL) daily in one or two divided doses	10 to 25 mg (10 to 25 mL) daily in one or two divided doses
Short-term management of insomnia, pre-surgical or obstetrical sedation	20 to 50 mg (20 to 50 mL) at night		
Night sedation or premedication		15 to 20 mg (15 to 20 mL) at bedtime	20 to 25 mg (20 to 25 mL) at bedtime
Prevention of	20 to 25 mg (20 to 25 mL) the	5 mg (5 mL) given the	10 mg (10 mL) given

motion sickness	night before traveling followed by a similar dose the following morning if necessary Or 25 mg one-half to one hour before anticipated travel, repeated 8 to 12 hours later if necessary	night before the journey and repeated on the following morning if necessary	the night before the journey and repeated on the following morning if necessary
Active therapy of nausea and vomiting	25 mg (25 mL); 12.5 to 25 mg doses may be repeated, as necessary, at 4 to 6 hour intervals	0.25-0.5 mg/kg 4 to 6 times daily	25 mg (25 mL)
Prophylaxis of nausea and vomiting, as during surgery and the postoperative period	25 mg (25 mL) repeated at 4 to 6 hours intervals, as necessary		
For nausea and vomiting arising from causes such as labyrinthitis	25 mg (25 mL) at night is usually adequate; this may be increased to 50 or 75 mg at night or to 25 mg two or three times daily if necessary to a maximum of 100 mg daily		
Preoperative use to relieve apprehension and produce a quiet sleep	50 mg (50 mL) the night before surgery	12.5 to 25 mg (12.5 to 25 mL) the night before surgery	
Postoperative sedation and adjunctive use with analgesics	25 to 50 mg (25 to 50 mL)	12.5 to 25 mg (12.5 to 25 mL)	

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- History of hypersensitivity to any of the components
- Hypersensitivity or cross sensitivity with other drugs especially other phenothiazine derivatives
- Greatly depressed states due to central nervous system depressants
- Children under 2 years of age

Precautions

- This drug should not be used in pediatric patients less than 2 years of age. Caution should be exercised when administering to pediatric patients 2 years of age and older.
- This drug may cause marked drowsiness or impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle, operating machinery, or bike riding.
- The use of this drug should be avoided in patients with compromised respiratory function.

- This drug should be used with caution in elderly patients and in persons with seizure disorders, bone marrow depression, narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, intestinal obstruction, bladder-neck obstruction, cardiovascular disease, impairment of liver or renal function.
- Antiemetics are not recommended for treatment of uncomplicated vomiting in pediatric patients, and their use should be limited to prolonged vomiting of known etiology.
- Avoid prolonged exposure to sunlight during the treatment.
- Some diagnostic pregnancy tests may result in false-negative or false-positive interpretations in patients treated with promethazine.
- In case of pregnancy or lactation, consult your doctor about the use of this medicine. It is recommended to avoid using this medication during pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug may increase, prolong, or intensify the sedative action of other central nervous system depressants such as alcohol, sedatives/ hypnotics, narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers.

Concomitant use of other agents with anticholinergic properties should be undertaken with caution.

Use with caution with monoamine oxidase inhibitors and local anesthetics.

Adverse reactions

This drug is usually well tolerated when used as directed.

Drowsiness is the most prominent effect. Other reported effects include: sedation, somnolence, blurred vision, dizziness, confusion, disorientation, fatigue, euphoria, nervousness, diplopia, tremors, excitation, increased or decreased blood pressure, tachycardia, bradycardia, dermatitis, hematologic disorders, photosensitivity, dry mouth, nausea, vomiting, asthma, respiratory depression, apnea, neuroleptic malignant syndrome, extrapyramidal symptoms, hallucinations, convulsions, jaundice and edema.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

PROMETHAZINE hydrochloride, promethazine HCl 5 mg/5 mL syrup, bottle of 120 mL

Revision date: 06/2010

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