Promethazine HCL 12,5mg, 25mg, suppository

Promethazine Hydrochloride Suppositories USP, 12.5 mg and 25 mg

Description
Each rectal suppository contains 12.5 mg or 25 mg promethazine HCl with ascorbyl palmitate, cocoa butter, colloidal silicon dioxide, and white wax. Promethazine Hydrochloride Suppositories are for rectal administration only.

Clinical Pharmacology
Promethazine is a phenothiazine derivative, which differs structurally from the antipsychotic phenothiazines by the presence of a branched side chain and no ring substitution. It is thought that this configuration is responsible for its relative lack (1/10 that of chlorpromazine) of dopamine antagonist properties. Promethazine is an H1 receptor blocking agent. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic effects.

Promethazine is well absorbed from the gastrointestinal tract. Clinical effects are apparent within 20 minutes after oral administration and generally last four to six hours, although they may persist as long as 12 hours. Promethazine is metabolized by the liver to a variety of compounds; the sulfoxides of promethazine and N-demethylpromethazine are the predominant metabolites appearing in the urine.

Indications And Usage

Promethazine HCl Suppositories are useful for:

- Perennial and seasonal allergic rhinitis.
- Vasomotor rhinitis.
- Allergic conjunctivitis due to inhalant allergens and foods.
- Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.
- Amelioration of allergic reactions to blood or plasma.
- Dermographism.
- Anaphylactic reactions, as adjunctive therapy to epinephrine and other standard measures, after the acute manifestations have been controlled.
- Preoperative, postoperative, or obstetric sedation.
- Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery.
- Therapy adjunctive to meperidine or other 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.

Contraindications
Promethazine HCl Suppositories are contraindicated for use in pediatric patients less than two years of age.

Promethazine HCl Suppositories are contraindicated in comatose states, and in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines. Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms including asthma.

Warnings

- Promethazine hcl suppositories should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.
- Postmarketing cases of respiratory depression, including fatalities, have been reported with use of promethazine hcl suppositories in pediatric patients less than 2 years of age. A wide range of weight-based doses of promethazine hcl suppositories have resulted in respiratory depression in these patients.
- Caution should be exercised when administering promethazine hcl to pediatric patients 2 years of age and older. It is recommended that the lowest effective dose of promethazine hcl be used in pediatric patients 2 years of age and older and concomitant administration of other drugs with respiratory depressant effects be avoided.

CNS Depression
Promethazine HCl Suppositories may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. The impairment may be amplified by concomitant use of other central-nervous-system depressants such as alcohol, sedatives/hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers; therefore such agents should either be eliminated or given in reduced dosage in the presence of promethazine HCl (see PRECAUTIONS - Information for Patients and Drug Interactions).

Respiratory Depression
Promethazine HCl Suppositories may lead to potentially fatal respiratory depression. Use of Promethazine HCl Suppositories in patients with compromised respiratory function (e.g., COPD, sleep apnea) should be avoided.

Lower Seizure Threshold
Promethazine HCl Suppositories may lower seizure threshold. It should be used with caution in persons with seizure disorders or in persons who are using concomitant medications, such as narcotics or local anesthetics, which may also affect seizure threshold.

Bone-Marrow Depression
Promethazine HCl Suppositories should be used with caution in patients with bone-marrow depression. Leukopenia and agranulocytosis have been reported, usually when promethazine HCl has been used in association with other known marrow-toxic agents.

Neuroleptic Malignant Syndrome
A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with promethazine HCl alone or in combination with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmias).

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system (CNS) pathology.

The management of NMS should include 1) immediate discontinuation of promethazine HCl, antipsychotic drugs, if any, and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. Since recurrences of NMS have been reported with phenothiazines, the reintroduction of promethazine HCl should be carefully considered.

Use in Pediatric Patients
Promethazine hcl suppositories are contraindicated for the use in pediatric patients less than two years of age.

Precautions

General
Drugs having anticholinergic properties should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, and bladder-neck obstruction. Promethazine HCl Suppositories should be used cautiously in persons with cardiovascular disease or with impairment of liver function.

Information for Patients
Promethazine HCl Suppositories 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 or operating machinery. The use of alcohol or other central-nervous-system depressants such as sedatives/ hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers, may enhance impairment (see WARNINGS - CNS Depression and PRECAUTIONS – Drug Interactions). Pediatric patients should be supervised to avoid potential harm in bike riding or other hazardous activities. Patients should be advised to report any involuntary muscle movements.

Drug Interactions

CNS Depressants
Promethazine HCl Suppositories may increase, prolong, or intensify the sedative action of other central-nervous-system depressants, such as alcohol, sedatives/hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers; therefore, such agents should be avoided or administered in reduced dosage to patients receiving promethazine HCl. When given concomitantly with Promethazine HCl Suppositories, the dose of barbiturates should be reduced by at least one-half, and the dose of narcotics should be reduced by one-quarter to one-half. Dosage must be individualized. Excessive amounts of promethazine HCl relative to a narcotic may lead to restlessness and motor hyperactivity in the patient with pain; these symptoms usually disappear with adequate control of the pain.

Epinephrine
Because of the potential for promethazine HCl to reverse epinephrine's vasopressor effect, epinephrine should NOT be used to treat hypotension associated with Promethazine HCl Suppositories overdose.

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

Monoamine Oxidase Inhibitors (MAOI)
Drug interactions, including an increased incidence of extrapyramidal effects, have been reported when some MAOI and phenothiazines are used concomitantly. This possibility should be considered with Promethazine HCl Suppositories.

Dosage And Administration

Promethazine HCl Suppositories are contraindicated for children under 2 years of age (see WARNINGS - Black Box Warning and Use in Pediatric Patients).

Promethazine HCl Suppositories are for rectal administration only.

Allergy: The average dose is 25 mg taken before retiring; however, 12.5 mg may be taken before meals and on retiring, if necessary. Single 25 mg doses at bedtime or 6.25 to 12.5 mg taken three times daily will usually suffice. After initiation of treatment in children or adults, dosage should be adjusted to the smallest amount adequate to relieve symptoms. The administration of promethazine hydrochloride in 25 mg doses will control minor transfusion reactions of an allergic nature.

Motion Sickness: The average adult dose is 25 mg taken twice daily. The initial dose should be taken one-half to one hour before anticipated travel and be repeated 8 to 12 hours later, if necessary. On succeeding days of travel, it is recommended that 25 mg be given on arising and again before the evening meal. For children, Promethazine HCl Rectal Suppositories, 12.5 to 25 mg, twice daily, may be administered.

Nausea and Vomiting: Antiemetics should not be used in vomiting of unknown etiology in children and adolescents (see WARNINGS - Use In Pediatric Patients).

The average effective dose of promethazine HCl for the active therapy of nausea and vomiting in children or adults is 25 mg; 12.5 to 25 mg doses may be repeated, as necessary, at 4 to 6 hour intervals.

For nausea and vomiting in children, the usual dose is 0.5 mg per pound of body weight, and the dose should be adjusted to the age and weight of the patient and the severity of the condition being treated.

For prophylaxis of nausea and vomiting, as during surgery and the postoperative period, the average dose is 25 mg repeated at 4 to 6 hour intervals, as necessary.

Sedation: This product relieves apprehension and induces a quiet sleep from which the patient can be easily aroused. Administration of 12.5 to 25 mg Promethazine HCl by rectal suppository at bedtime will provide sedation in children. Adults usually require 25 to 50 mg for nighttime, presurgical, or obstetrical sedation.

Pre- and Postoperative Use: Promethazine HCl in 12.5 to 25 mg doses for children and 50 mg doses for adults the night before surgery relieves apprehension and produces a quiet sleep.

For preoperative medication, children require doses of 0.5 mg per pound of body weight in combination with an appropriately reduced dose of narcotic or barbiturate and the appropriate dose of an atropine-like drug. Usual adult dosage is 50 mg promethazine HCl with an appropriately reduced dose of narcotic or barbiturate and the required amount of a belladonna alkaloid.

Postoperative sedation and adjunctive use with analgesics may be obtained by the administration of 12.5 to 25 mg in children and 25 to 50 mg doses in adults.

Promethazine HCl Rectal Suppositories are not recommended for children under 2 years of age.

Storage
Store refrigerated between 2°-8°C (36°-46°F).