

PROMETAL[®]

Tablets

DESCRIPTION : Each tablet contains : Promethazine hydrochloride 25 mg.

CLINICAL PHARMACOLOGY : 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

PROMETAL[®] is 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 : **PROMETAL[®]** tablets are contraindicated in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or other phenothiazines.

Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms including asthma.

ADVERSE REACTIONS

Central Nervous System : Drowsiness is the most prominent CNS effect of this drug. Sedation, somnolence, blurred vision, dizziness, confusion, disorientation, and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion, lassitude, tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsive seizures, excitation, catatonic-like states, hysteria. Hallucinations have also been reported.

Cardiovascular : Increased or decreased blood pressure, tachycardia, bradycardia, faintness.

Dermatologic : Dermatitis, photosensitivity, urticaria.

Hematologic : Leukopenia, thrombocytopenia, agranulocytosis

Gastrointestinal : Dry mouth, nausea, vomiting, jaundice.

Respiratory: Asthma, nasal stuffiness, respiratory depression (potentially fatal) and apnea (potentially fatal).

Other : Angioneurotic edema. Neuroleptic malignant syndrome (potentially fatal) has been reported .

Paradoxical Reactions (Overdosage) : Hyperexcitability & abnormal movements, which have been reported in patients following a single administration of promethazine HCL. Consideration should be given to the discontinuation of promethazine HCL and to the use of other drugs, if these reactions continue. Respiratory depression , nightmares , delirium , and agitated behavior have also been reported in some of these patients.

DOSAGE AND ADMINISTRATION

PROMETAL[®] tablets are not recommended for children under 2 years of age.

Allergy

The average oral 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 HCL in 25-mg doses will control minor transfusion 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, 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.

The average effective dose of **PROMETAL[®]** tablets for the active therapy of nausea and vomiting in children and adults is 25 mg.

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 the oral route at bedtime will provide sedation in children . Adults usually require 25 to 50 mg for night time, presurgical, or obstetrical sedation.

HOW SUPPLIED

Blister pack of 20 tablets.

Keep tightly closed.

Store at controlled room temperature, between 20°C and 25°C .

Protect form light.

Keep out of the reach of children.

Revised 09 / 2008



PHARMADEX S.A.L.
KAHALE - LEBANON