Promethazine Hydrochloride Suppositories, USP

Rx Only

DESCRIPTION

Promethazine hydrochloride is an H1 receptor blocking agent. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic effects.

Promethazine HCl occurs as a white to faint yellow, practically odorless, crystalline powder, which slowly oxidizes and forms crystals on prolonged exposure to air. It is soluble in water and freely miscible in alcohol.

Dosage Form

Promethazine HCl Suppositories, USP, are for rectal administration only.

Each rectal suppository contains 12.5 mg or 25 mg promethazine HCl with ascorbyl palmitate, colloidal silicon dioxide, white wax, hard fat, and glyceryl monostearate. Promethazine HCl Suppositories, USP are for rectal administration only.

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Promethazine HCl is a white to off-white, practically inactive crystals, powder which slowly oxidizes and forms crystals on prolonged exposure to air.

INDICATIONS AND USAGE

Promethazine HCl Suppositories are useful for:

Personal and sexual ailments

Sedation

Promethazine HCl Suppositories may be used in patients with compromised respiratory function (e.g., COPD, sleep apnea) should be avoided.

Lower Urogenital Tract

Promethazine HCl Suppositories may be used in patients with compromised respiratory function (e.g., COPD, sleep apnea) should be avoided.

Bone-Marrow Depression

Promethazine HCl Suppositories should be used cautiously in patients with bone-marrow depression. Leukopenia and agranulocytosis have been reported.

Neuropsychiatric Syndromes

A potentially fatal syndrome 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).

Hypotension

Promethazine HCl Suppositories should be used cautiously in patients with cardiovascular disease or with impairment of liver function.

Administration of promethazine HCl has been associated with reported cholestatic jaundice.

Oral absorption of promethazine is minimal, and the drug is not recommended for oral administration.

Contraindications

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.

Anticholinergics should be used with caution in patients with bone-marrow depression. Leukopenia and agranulocytosis have been reported.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases where the clinical manifestations dominate over the laboratory findings. Therefore, a high index of suspicion is required.

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### DOSAGE AND ADMINISTRATION

**Motion Sickness**

Promethazine HCl suppositories may be administered at bedtime to prevent a pre- and/or postoperative state of nausea and vomiting. Usual adult dosage is 12.5 to 25 mg taken before retiring; however, 12.5 mg may be taken before meals and on retiring, if necessary. Single 25-mg doses at 4- to 6-hour intervals, as necessary, may be repeated.

**Nausea and Vomiting**

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.

**Paralytic Reactions**

**Signs and symptoms of overdosage with promethazine HCl range from mild depression of the central nervous system and cardiovascular system to severe respiratory depression in rare instances.** Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, treatment of respiratory depression, or in cases where the drug is life-saving, does the necessity exist for providing something other than symptomatic and supportive treatment. Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, treatment of respiratory depression, or in cases where the drug is life-saving, does the necessity exist for providing something other than symptomatic and supportive treatment. Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, treatment of respiratory depression, or in cases where the drug is life-saving, does the necessity exist for providing something other than symptomatic and supportive treatment. Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, treatment of respiratory depression, or in cases where the drug is life-saving, does the necessity exist for providing something other than symptomatic and supportive treatment.

**Presentation**

**Promethazine HCl Rectal Suppositories are contraindicated for use in pediatric patients less than two years of age (see WARNINGS – Black Box Warning and Use in Pediatric Patients).**