Promethazine Hydrochloride Injection, USP

25 mg for Deep Intramuscular or Intravenous Use
50 mg for Deep Intramuscular Use

Promethazine Hydrochloride Injection is contraindicated for use in pediatric patients less than 2 years of age (see WARNINGS - Respiratory Depression). Caution should be exercised when administering promethazine hydrochloride injection to pediatric patients 2 years of age or older. It is recommended that the lowest effective dose of promethazine hydrochloride injection be used (see WARNINGS - Respiratory Depression).

Pediatric Patients

Promethazine hydrochloride injection is contraindicated for use in pediatric patients less than 2 years of age (see WARNINGS - Respiratory Depression). Caution should be exercised when administering promethazine hydrochloride injection to pediatric patients 2 years of age or older. It is recommended that the lowest effective dose of promethazine hydrochloride injection be used (see WARNINGS - Respiratory Depression). In children 2 years of age and older, the dosage should be reduced (at least one third of the suggested adult dose). As an adjunct to premedication, the suggested dose is 1.1 mg per kg of body weight in combination with an appropriate analgesic and the appropriate dose of an atropine-like drug (see PRECAUTIONS - Drug Interactions). Antiemetics should not be used in vomiting of unknown etiology in pediatric patients.

HOW SUPPLIED

Promethazine Hydrochloride Injection, USP - 25 mg/mL, 1 mL fill in a 1 mL ampul (NDC 39822-5525-2)
packaged in cartons of 25 (NDC 39822-5525-3)

Promethazine Hydrochloride Injection, USP - 50 mg/mL, 1 mL fill in a 1 mL ampul (NDC 39822-5550-5)
packaged in cartons of 25 (NDC 39822-5550-6)

Store at 20º to 25ºC (68º to 77ºF) [See USP Controlled Room Temperature].
Protect from light. Keep covered in carton until time of use.
Do not use if solution has developed color or contains a precipitate.

Please contact customer service at 866-390-4411 or visit our website at www.x-gen.us

Certified Women's Business Enterprise
Promethazine hydrochloride is a phenothiazine derivative which possesses antihistaminic, sedative, antimotion-sickness, and dopamine antagonist properties. Clinical effects are generally apparent within 5 minutes of an intramuscular injection. Promethazine hydrochloride injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions (including anaphylactic reactions) in patients with a history of sulfite sensitivity. Because of the potential for fatal respiratory depression, post-marketing cases of respiratory depression, including fatalities, have been reported with use of promethazine in pediatric patients less than 2 years of age. A wide range of weight-based doses of promethazine hydrochloride injection have been reported with use of promethazine in pediatric patients less than 2 years of age. A 4-fold range of weight-based doses of promethazine hydrochloride injection have been reported with use of promethazine in pediatric patients less than 2 years of age.

Promethazine hydrochloride injection is a clear, colorless solution. The product is light sensitive. It should be inspected for color, turbidity, and foreign matter at each administration. Irritation and damage can result from perivascular extravasation, unintentional intra-arterial injection, injection site reactions, and tissue necrosis. In some cases, surgical removal of necrotic/tissue may be required. Consideration should be given to the discontinuation of promethazine hydrochloride injection. Consideration should be given to the discontinuation of promethazine hydrochloride injection.

**INDICATIONS AND USAGE**

Promethazine hydrochloride injection is indicated for:

- Anxiety as an adjunct to antiemetics and other standard measures after the acute symptoms have been established.
- As an anxiolytic in the management of anxiety states.
- Sedation in patients with excessive restlessness, apprehension, or insomnia, particularly if these states are due to environmental stress.
- Sedation in patients with environmental stress. Tension, anxiety, and restlessness often accompany noise, light, or heat as well as other environmental factors.
- As a preoperative sedative when used with an appropriate analgesic or as an anesthetic adjuvant.
- To provide sedation during diagnostic and therapeutic procedures when used with an appropriate analgesic.

**CONTRAINDICATIONS**

- Allergic reactions to promethazine derivatives, phenothiazines, and related compounds.
- Known sensitivity to other phenothiazine antipsychotics.
- Patients with narrow-angle glaucoma.
- Patients with diverticulitis, ulcerative colitis, or inflammatory bowel disease.
- Patients with asthma or other respiratory disease.
- Patients with overactive thyroid gland.
- Patients with diabetes mellitus.
- Patients with phenothiazine sensitivity.
- Patients with prostatic hypertrophy.
- Patients with renal or hepatic insufficiency.
- Patients with history of narcolepsy.
- Patients with malignancies.
- Patients with known or suspected serum sickness.
- Patients with known or suspected pernicious anemia.
- Patients with known or suspected porphyria.
- Patients with known or suspected multiple sclerosis.
- Patients with known or suspected myasthenia gravis.
- Patients with known or suspected hypothysis.
- Patients with known or suspected hypothyroidism.
- Patients with known or suspected hyperthyroidism.
- Patients with known or suspected hypothermia.
- Patients with known or suspected hyperthermia.
- Patients with known or suspected hypotension.
- Patients with known or suspected hypertension.
- Patients with known or suspected hypoglycemia.
- Patients with known or suspected hyperglycemia.
- Patients with known or suspected hypokalemia.
- Patients with known or suspected hyperkalemia.
- Patients with known or suspected hypophosphatemia.
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