PROMETAZINA

Prometazina Cloridrato Expectorante Xarope

6.25 mg/5 ml

Composition:
Each 5 ml contains:

Promethazine Hydrochloride BP	6.25 mg
Excipients	q.s.
Flavored syrup base	q.s.
Approved color used	

Pharmaceutical form:
Oral liquid.

Therapeutic indications:
Promethazine hydrochloride expectorant syrup is indicated for:
- Symptomatic relief of allergies such as hay fever and urticaria, and insomnia associated with urticaria and pruritus.
- Emergency treatment of anaphylactic reactions.
- Sedation (short-term use).
- Nausea, vomiting, vertigo, labyrinthine disorders, and motion sickness.

Dosage and method of administration:
Dosage:
For symptomatic relief of allergies such as hay fever and urticaria, insomnia associated with urticaria, and pruritus:
Children aged 2 to 4 years: 5 mg twice daily; alternatively, 5 to 15 mg once daily (to be taken at night).
Children aged 5 to 9 years: 5 to 10 mg twice daily; alternatively, 10 to 25 mg once daily (to be taken at night).
Children aged 10 to 17 years: 10 to 20 mg 2 to 3 times daily; alternatively, 25 mg once daily (to be taken at night), increased if necessary to 25 mg twice daily.
Adults: 10–20 mg 2–3 times daily.

For sedation (short-term use):
Children aged 2 to 4 years: 15 to 20 mg.
Children aged 5 to 9 years: 20 to 25 mg.
Children aged 10 to 17 years: 25 to 50 mg.
Adults: 25–50 mg.

For nausea, vomiting, vertigo, labyrinthine disorders, and motion sickness:
Children aged 2 to 4 years, 5 to 9 years, and 10 to 17 years: 5 mg, 10 mg, and 20 to 25 mg, respectively; to be taken at bedtime the night before the journey, and repeated the following morning if necessary.
Adults: 20–25 mg; to be taken at bedtime the night before the journey, and repeated the following morning if necessary.

Method of administration:
For oral administration.
SHAKE WELL BEFORE USE.

Contraindications:
Promethazine hydrochloride expectorant syrup is contraindicated; - for use in pediatric patients under two years of age.
- in comatose states and in individuals known to be hypersensitive or who have had an idiosyncratic reaction to promethazine or other phenothiazines.
Antihistamines are contraindicated for use in treating lower respiratory tract symptoms, including asthma.
Warnings and precautions:
Warnings:

PROMETHAZINE MUST NOT BE USED IN PEDIATRIC PATIENTS UNDER 2 YEARS OF AGE DUE TO THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION.

POST-MARKETING CASES OF RESPIRATORY DEPRESSION, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF PROMETHAZINE IN PEDIATRIC PATIENTS UNDER 2 YEARS OF AGE. A WIDE RANGE OF WEIGHT-BASED DOSES OF PROMETHAZINE WILL RESULT IN RESPIRATORY DEPRESSION IN THESE PATIENTS.

CAUTION SHOULD BE EXERCISED WHEN ADMINISTERING PROMETHAZINE TO PEDIATRIC PATIENTS 2 YEARS OF AGE OR OLDER. IT IS RECOMMENDED THAT THE LOWEST EFFECTIVE DOSE OF PROMETHAZINE BE USED IN PEDIATRIC PATIENTS 2 YEARS OF AGE OR OLDER AND THAT CONCOMITANT ADMINISTRATION OF OTHER MEDICATIONS WITH RESPIRATORY DEPRESSANT EFFECTS BE AVOIDED.

CNS Depression:
Promethazine hydrochloride expectorant syrup may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery.

Respiratory Depression:
Promethazine hydrochloride expectorant syrup may cause potentially fatal respiratory depression. The use of promethazine hydrochloride expectorant syrup in patients with compromised respiratory function (e.g., COPD, sleep apnea) should be avoided.

Lowered seizure threshold:
Promethazine hydrochloride expectorant syrup may lower the seizure threshold. It should be used with caution in individuals with seizure disorders or in those taking concomitant medications—such as narcotics or local anesthetics—that may also affect the seizure threshold.

Bone marrow depression:
Promethazine hydrochloride expectorant syrup should be used with caution in patients with bone marrow depression. Leukopenia and agranulocytosis have been reported, generally when promethazine (promethazine hydrochloride) was used in conjunction with other known bone-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 hydrochloride alone or in combination with antipsychotic medications.

Use in pediatric patients
CONCOMITANT ADMINISTRATION OF PROMETHAZINE PRODUCTS WITH OTHER RESPIRATORY DEPRESSANTS HAS BEEN ASSOCIATED WITH RESPIRATORY DEPRESSION AND, AT TIMES, DEATH, IN PEDIATRIC PATIENTS.

Antiemetics are not recommended for the treatment of uncomplicated vomiting in pediatric patients, and their use should be limited to prolonged vomiting of known etiology. Extrapyramidal symptoms that may occur following the administration of promethazine hydrochloride expectorant syrup may be confused with CNS signs of an undiagnosed primary illness, e.g., encephalopathy or Reye's syndrome. The use of promethazine syrup should be avoided in pediatric patients whose signs and symptoms might suggest Reye's syndrome or other hepatic diseases.

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

Precautions:
Drugs with anticholinergic properties should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, and bladder-neck obstruction.
It should be used with caution in individuals with cardiovascular disease or impaired hepatic function.

Information for patients:
Promethazine hydrochloride expectorant syrup 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. Patients should be advised to report any involuntary muscle movements. Avoid prolonged exposure to the sun.

Drug interactions:
CNS depressants:
Promethazine hydrochloride expectorant syrup 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 doses to patients receiving promethazine hydrochloride.

Epinephrine:
Due to the potential for promethazine to reverse the vasopressor effect of epinephrine, epinephrine should NOT be used to treat hypotension associated with promethazine hydrochloride expectorant syrup overdose.

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

Monoamine oxidase inhibitors (MAOIs).

Drug interactions, including an increased incidence of extrapyramidal effects, have been reported when certain MAOIs and phenothiazines are used concomitantly.

Adverse effects:
Central Nervous System:
Drowsiness is the most prominent CNS effect. 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, convulsions, excitation, catatonic-like states, hysteria. Hallucinations may occur.
Cardiovascular: Increase or decrease in blood pressure, tachycardia, bradycardia, fainting.
Dermatological: Dermatitis, photosensitivity, urticaria. Hematologic: Leukopenia, thrombocytopenia, thrombocytopenic purpura, agranulocytosis.
Gastrointestinal: Dry mouth, nausea, vomiting, jaundice.
Respiratory: Asthma, nasal congestion, respiratory depression (potentially fatal), and apnea (potentially fatal).
Other: Angioedema. Neuroleptic malignant syndrome (potentially fatal) may occur.
Paradoxical reactions:
Hyperexcitability and abnormal movements may be observed in patients following a single administration of promethazine hydrochloride. Discontinuation of promethazine hydrochloride and the use of alternative medications should be considered if these reactions occur. Respiratory depression, nightmares, delirium, and agitated behavior have also been reported in some of these patients.

Overdose:
Signs and symptoms of promethazine hydrochloride overdose range from mild central nervous system and cardiovascular system depression to profound hypotension, respiratory depression, unconsciousness, and sudden death. Other reported reactions include hyperreflexia, hypertonia, ataxia, athetosis, and extensor-plantar reflexes (Babinski reflex).
Stimulation may be evident, particularly in children and geriatric patients. Seizures may occur rarely. A paradoxical-type reaction has been reported in children receiving single oral doses of 75 mg to 125 mg, characterized by hyperexcitability and nightmares.
Atropine-like signs and symptoms—dry mouth, fixed and dilated pupils, flushing, as well as gastrointestinal symptoms—may occur.

Treatment:
Treatment of overdose is essentially symptomatic and supportive. Vital signs—including respiration, pulse, blood pressure, temperature, and ECG—should be monitored, particularly in cases of extreme overdose or individual hypersensitivity. Activated charcoal may be administered orally or via gastric lavage; sodium or magnesium sulfate may be given orally as a cathartic. Diazepam may be used to control seizures. Acidosis and electrolyte imbalances must be corrected. Note that the depressant effects of promethazine HCl are not reversed by naloxone. Avoid analeptics, which may induce seizures.
The treatment of choice for resulting hypotension is the administration of intravenous fluids, accompanied by repositioning if indicated. If vasopressors are considered for severe hypotension unresponsive to intravenous fluids and repositioning, the administration of norepinephrine or phenylephrine should be considered. EPINEPHRINE SHOULD NOT BE USED, as its use in patients with partial adrenergic blockade may further lower blood pressure. Extrapyramidal reactions may be treated with anticholinergic antiparkinsonian agents, diphenhydramine, or barbiturates. Oxygen may also be administered.
Limited experience with dialysis indicates that it is not useful.

Storage:
Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Presentation:
100 mL bottle packaged in a printed carton with a package insert.

Manufactured by :
US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in