

PROMENE 25MG TABLET

Composition:

Each film coated tablet contains Promethazine Hydrochloride 25mg

Description:

A blue coloured round shaped film coated tablet

Pharmacodynamics:

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

Pharmacokinetics:

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.

Indication:

As symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis, urticaria and anaphylactic reactions to drugs and foreign proteins.

As an adjunct in preoperative sedation in surgery and obstetrics

As an antiemetic

For short term use:

Sedation and treatment for insomnia in adults

As a paediatric sedative

Recommended dose:

Not for use in children under the age of 2 years because the safety of such is not established.

As an antihistamine in allergy:

Children over 5-10 years	25mg as a single dose* maximum daily dose 25mg
Children over 10 years and adults (including elderly)	25 mg as a single dose* Increasing to a maximum of 25 mg bd as required.

* Single dose are best taken at night.

As an antiemetic:

Children over 10 years and adults (including elderly)	25 mg to be taken the night before the journey. To be repeated after 6-8 hours as required.
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Short term sedation:

Children 5 to 10 years	25mg as a single night time dose.
Children over 10 years and adults (including elderly)	25mg or 50mg as a single night time dose.

Route of administration:

Oral administration

Contraindication:

PROMENE should not be used in patients in coma or suffering from CNS depression of any

cause. PROMENE should not be given to patients with a known hypersensitivity to promethazine or to any of the excipients. Promethazine is contraindicated for use in children less than two years of age because of the potential for fatal respiratory depression. PROMENE should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

Warning and precautions:

PROMENE should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, and bladder-neck obstruction. PROMENE should be used cautiously in persons with cardiovascular disease or with impairment of liver function.

PROMENE 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

PROMENE may thicken or dry lung secretions and impair expectoration. It should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis.

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

PROMENE should not be used for longer than 7 days without seeking medical advice. Avoid prolonged exposure to the sun.

When used for treatment of cough and cold:

- a) It should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.
- b) To be used with caution and doctor's/ pharmacist's advice in children 2 to 6 years of age.

Interaction with other medicaments:

PROMENE will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Promethazine may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results.

Promethazine should be discontinued at least 72 hours before the start of skin tests as it may inhibit the cutaneous histamine response thus producing false-negative results.

Pregnancy and lactation:

PROMENE should not be used in pregnancy unless the physician considers it essential. The use of PROMENE is not recommended in the 2 week prior to delivery in view of the risk of irritability and excitement in the neonate.

Available evidence suggests that amount excreted in milk is insignificant.

Side effects:

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, thrombocytopenic purpura, 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 also been reported.

Overdosage:

Signs and symptoms of overdosage with promethazine hydrochloride range from mild depression of the central nervous system and cardiovascular system to profound hypotension, respiratory depression, and unconsciousness, and sudden death. Other reported reactions include hyperreflexia, hypertonia, ataxia, athetosis, and extensor-plantar reflexes (Babinski reflex).

Stimulation may be evident, especially in children and geriatric patients. Convulsions may rarely occur. A paradoxical-type reaction has been reported in children receiving single doses of 75 mg to 125 mg orally, characterized by hyperexcitability and nightmares.

Atropine-like signs and symptoms - dry mouth, fixed, dilated pupils, flushing, as well as gastrointestinal symptoms - may occur.

Treatment

Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, including respiration, pulse, blood pressure, temperature, and EKG, need to be monitored. Activated charcoal orally or by lavage may be given, or sodium or magnesium sulfate orally as a cathartic. Attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. Diazepam may be used to control convulsions. Acidosis and electrolyte losses should be corrected. Note that any depressant effects of promethazine HCl are not reversed by naloxone. Avoid analeptics which may cause convulsions. The treatment of choice for resulting hypotension is administration of intravenous fluids, accompanied by repositioning if indicated. In the event that vasopressors are considered for the management of severe hypotension which does not respond to intravenous fluids and repositioning, the administration of norepinephrine or phenylephrine should be considered.

EPINEPHRINE SHOULD NOT BE USED, since its use in patients with partial adrenergic blockade may further lower the 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 helpful.

Storage:

Store below 30°C.

Effects on Ability to Drive and Use Machine:

Patients should be advised that if they feel drowsy they should not drive or operate heavy machinery.

Presentation:

Blister of 10 tablets. Box of 30, 100, 500 or 1000 tablets

Manufactured by:

Noripharma Sdn. Bhd. Lot 5030, 200701034604 (792633-A)

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5 ½ Mile off Jalan Meru,

41050 Klang,

Selangor Malaysia

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