

Promehil

Promethazine Hydrochloride

COMPOSITION

Each 5 ml elixir contains Promethazine Hydrochloride USP 5 mg

INDICATION

- Potent long-acting antihistamine with additional anti-emetic and sedative/calming effects.
- Indicated in symptomatic treatment of allergic conditions of the respiratory tract and skin. Sensitization reactions to drug or foreign proteins, anaphylactic reactions.
- For sedation, allergic rhinitis, urticaria and insomnia.
- As an adjunct in pre-operative sedation in surgery and obstetrics.
- As a paediatric sedative.

DOSAGE & ADMINISTRATION

Adults

Oral administration: Initial dose one 25 mg tablet at night; may be increased to two or three 25 mg tablets at night if necessary. In allergic conditions more frequently administration, twice or three times daily, may be necessary, starting with one or two 10 mg tablets and increasing as required.

Elderly

No specific dosage recommendations.

Children

They may be treated more conveniently by the elixir containing 5 mg per 5 ml.

As an antihistamine in allergy:

Children of 2 - 5 years:.....5 - 15 mg

Children of 5 - 10 years:.....10 - 25 mg

In case where two doses in 24 hours are required the lower dose stated should be given.

As a sedative:

Children of 2 - 5 years:.....15 - 20 mg

Children of 5 - 10 years:.....20 - 25 mg

Given as a single night-time dose.

CONTRAINDICATION

- **Promehil is contraindicated for use in children less than two years of age**
- **Hypersensitivity to promethazine or to any of the excipients.**
- **Promehil should not be used in patients who are in a coma or suffering from CNS depression of any cause. It must not be given to neonates or premature infants.**
- **Promehil should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.**

WARNINGS

Due to the risk of photosensitivity, exposure to the sun or ultraviolet light should be avoided during or shortly after treatment. Promethazine must not be used in children below two years of age due to the potential for fatal respiratory depression

There have been case reports of drug abuse with promethazine. The risk of abuse is greater in patients with a history of drug abuse.

PREGNANCY

There is epidemiological evidence for the safety of promethazine in pregnancy and animal studies have shown no hazard, nevertheless, it should not be used in pregnancy unless the physician considers it essential. The use of Phenergan is not recommended in the two weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

When promethazine has been given in high doses during late pregnancy, promethazine has caused prolonged neurological disturbances in the infant. Promethazine should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the fetus.

LACTATION

Promehil is excreted in breastmilk. There are risks of neonatal irritability and excitement. Promehil is not recommended for use in breastfeeding.

DRUG INTERACTIONS

Promehil may enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic, Alcohol should be avoided during drug treatment.

Promehil may interfere with immunologic urine pregnancy tests to produce false-positive or false-negative results.

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

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS

Promehil considerably affects the ability of driving a vehicle and operating machines. Ambulant patients receiving Promehil for the first time should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the central nervous effects of the drug and do not suffer from disorientation confusion or dizziness.

ADVERSE REACTIONS

Nervous system disorders:

Frequency Unknown: Neuroleptic Malignant Syndrome the elderly are particularly susceptible to the anticholinergic effects and confusion due to Phenergan®, somnolence, dizziness, headaches, extrapyramidal effects including muscle spasm, tic-like movements of the head and face.

A very serious and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor right away if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot.

Immune System Disorders

Frequency unknown : Allergic reactions, including urticaria, rash, pruritus, and anaphylaxis, have been reported.

Skin and Subcutaneous Tissue Disorders Frequency unknown: Photosensitivity reaction

Metabolism and Nutrition Disorders Frequency unknown: Anorexia Gastrointestinal Disorders

Frequency unknown: Epigastric discomfort, dry mouth

Eye Disorders

Frequency unknown: Blurred vision

Blood and Lymphatic System Disorders

Frequency unknown: Blood dyscrasias including hemolytic anemia, agranulocytosis

Renal and Urinary Disorders Frequency unknown: Urinary retention

Psychiatric Disorders

Frequency unknown: Infants, newborns and premature are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation

Cardiac Disorders:

Frequency unknown: Palpitations, arrhythmias

Vascular disorders:

Frequency unknown: Hypotension

Hepatobiliary disorders:

Frequency unknown: Jaundice

General Disorders and Administration Site Conditions: Frequency unknown: Tiredness

Use this drug only as recommended. Do not exceed the recommended dose. There have been case reports of promethazine abuse.

Do not take for longer than 10 days.

OVERDOSAGE

Symptoms of severe over dosage are variable. They are characterised in children by various combinations of excitation, ataxia, incoordination, athetosis and hallucinations, while adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children; coma or excitement may precede their occurrence. Tachycardia may develop. Cardiorespiratory depression is uncommon. If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used. Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or other suitable anticonvulsant.

Storage

Store below 30° C in a dry place. Keep away from light.

Warning

Prescription only medicine. To be used as directed by the physician. Keep out of reach of children.

Packaging

Each box contains 100 ml suspension in a PET bottle and a measuring cup.



Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
Bhangnathi, Sreepur, Gazipur, Bangladesh