PHENERGAN Injection
Promethazine hydrochloride B.P. 25 mg/ml injection

Presentation
PHENERGAN injection is a colourless solution containing 25 mg/ml promethazine hydrochloride. The injection also contains sodium sulphite and sodium metabisulphite.

Uses

Actions
PHENERGAN is a potent histaminic H1 antagonist with additional anti-emetic and sedative/calming properties. Its duration of action is 4-6 hours.

Pharmacokinetics
Promethazine is well absorbed after oral dosing and slowly excreted via urine and bile. It is distributed widely in the body. It enters the brain and crosses the placenta. Phenothiazines pass into breast milk at low concentrations.

Indications
1. The symptomatic treatment of allergic conditions of the upper respiratory tract and skin; sensitisation reactions to medicinal agents or foreign proteins; anaphylactic reactions.
2. As a hypnotic/sedative.
3. For pre-medication for its sedative/calming effect, anti-emetic action and anti-secretory effect.

Dosage and Administration

Adults

Parenteral administration
The usual adult dose is 25-50 mg by deep intramuscular injection or, in emergency, by slow intravenous injection after dilution of the 25mg/ml (2.5 w/v) solution to 10 times its volume with Water for Injections immediately before use. The maximum parenteral dose is 100 mg.

Elderly
No specific dosage recommendations.

Children
The safety and efficacy of promethazine has not been established in children under the age of 2 years.
For children 5 to 10 years half the oral dose, ie 6.25-12.5 may be given by deep intramuscular injection.

Contraindications
PHENERGAN should not be used in patients with hypersensitivity to promethazine or to any of the excipients. PHENERGAN should not be used in patients who are in a coma or suffering from CNS depression of any cause. PHENERGAN should not be given for
jaundice induced by other phenothiazine derivatives. It must not be given to neonates, premature infants or patients hypersensitive to phenothiazines. PHENERGAN should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days. This product should not be used in children under two years of age because safety of such use has not been established.

**Warnings and Precautions**

PHENERGAN may thicken or dry lung secretions and impair expectoration, it should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis. Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency. Caution should be exercised in patients with bladder neck or pyloroduodenal obstruction.

Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs, e.g. salicylates. It may also delay the early diagnosis of intestinal obstruction or raised intracranial pressure through the suppression of vomiting.

Accidental intra-arterial injection may lead to peripheral gangrene and necrosis while subcutaneous injections may lead to local necrosis. Promethazine should be used with caution in hypertensive crises patients. Promethazine may increase the severity of convulsions in epileptic patients. The elderly are more susceptible to the adverse effects of antihistamines, including antimuscarinic effects, sedation and hypotension.

**Pregnancy**

(Category C) 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.

**Lactation**

Available evidence suggests that the amount excreted in breast milk is very low. However, there are risks of neonatal irritability and excitement. It should not be used unless the physician considers it essential.

**Children**

The use of PHENERGAN should be avoided in children and adolescents with signs and symptoms suggestive of Reye’s Syndrome. Caution should be exercised when administering promethazine to children as there is potential for central and peripheral apnoea and reduced arousal. This product should not be used in children under two years of age because safety of such use has not been established.

**Driving**

Ambulant patients receiving PHENERGAN 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 medicine and do not suffer from disorientation, confusion or dizziness.
Adverse Effects
Side-effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness, and disorientation. Anticholinergic side-effects such as blurred vision, dry mouth and urinary retention occur occasionally. Newborn and premature infants are susceptible to the anticholinergic effects of promethazine while other children may display paradoxical hyperexcitability. The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine. Other side-effects include leucopenia, agranulocytosis, aplastic anaemia, thrombocytopenic purpura, marked irregular respiration, anorexia, gastric irritation, loss of appetite, nausea, vomiting, diarrhoea, constipation, palpitations, bradycardia, hypotension, arrhythmias, extrapyramidal effects, muscle spasms, tinnitus, euphoria, nervousness, insomnia, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, tardive dyskinesia and tic-like movements of the head and face. Jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Very rare cases of allergic reactions, including urticaria, rash, pruritis, and anaphylaxis have been reported. Photosensitive skin reactions have been reported; strong sunlight should be avoided during treatment. The preservatives used in PHENERGAN injection have been reported to cause hypersensitivity reactions, characterised by circulatory collapse with CNS depression, in certain susceptible individuals with allergic tendencies.

Interactions
PHENERGAN will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. PHENERGAN may interfere with immunologic urine pregnancy tests to produce false-positive or false-negative results. PHENERGAN 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. PHENERGAN injection has been known to increase glucose tolerance.

Overdosage
Symptoms of severe overdosage are variable. They are characterised in children by various combinations of excitation, ataxia, uncoordination, 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. Cardiorespiratory depression is uncommon. If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the anti-emetic 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.

Pharmaceutical Precautions
Protect from light. Store below 25°C. Solutions of PHENERGAN are incompatible with alkaline substances, which precipitate the insoluble promethazine base.

Medicine Classification
Prescription Medicine

#50889
Package Quantities
Injection: 25 mg/ml in boxes of 10 x 1 ml ampoules.

Further Information
PHENERGAN injection contains sulphites (sodium sulphite, sodium metabisulphite). Very rarely hypersensitivity reactions have been reported in susceptible persons.

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