DAWA-PROM®
Promethazine HCl BP Tablets/Syrup/Injection

Composition
Each film coated tablet contains: Promethazine HCl BP 2mg
Each 5ml syrup contains: Promethazine HCl 5mg
Each Ampoule contains: Promethazine HCl 25mg

Pharmacology
Promethazine, a phenothiazine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and some serotonin-antagonist properties.
It is usually given as the hydrochloride or teoclate. Promethazine embonate and promethazine maleate have also been given orally.
Promethazine dioxide (dioxopromethazine) has been used as the hydrochloride in eye and nasal drops. The antihistamine action has been reported to last for between 4 and 12 hours. Promethazine hydrochloride is used for the symptomatic relief of allergic conditions including urticaria and angioedema, rhinitis and conjunctivitis, and in pruritic skin disorders. It may be given intravenously as an adjunct in the emergency treatment of anaphylactic shock.

Pharmacokinetics
Promethazine is well absorbed after oral or intramuscular administration. Peak plasma concentrations have been observed 2 to 3 hours after administration by these routes, although there is low systemic bioavailability after oral administration, due to high first-pass metabolism in the liver. Promethazine crosses the blood-brain barrier and the placenta, and is distributed into breast milk. Values ranging from 76 to 93% have been reported for plasma-protein binding.
Promethazine undergoes extensive metabolism, predominantly to promethazine sulfoxide, and also to N-desmethylpromethazine. It is excreted slowly via the urine and bile, chiefly as metabolites. Elimination half-lives of 5 to 14 hours have been reported.

Indications
Promethazine hydrochloride is used for their antiemetic action in the prevention and treatment of nausea and vomiting in conditions such as motion sickness, drug-induced vomiting, and postoperative vomiting. It is also used for the symptomatic treatment of nausea and vertigo caused by Ménière's disease and other vestibular disorders Promethazine hydrochloride is also employed pre- and postoperatively in surgery and obstetrics for its sedative effects and for the relief of apprehension where it is often given with pethidine hydrochloride. Promethazine hydrochloride may be used for night-time sedation.

Precautions
Drowsiness is a prevalent with promethazine and those affected should not drive or operate machinery; alcohol should be avoided.
Because of its antimuscarinic actions, promethazine should be used with care in conditions such as angle-closure glaucoma, urinary retention, prostatic hyperplasia, or pyloroduodenal obstruction.
Occasional reports of convulsions in patients taking antihistamines suggest a need for caution in patients with epilepsy.
Caution is needed in hepatic impairment and renal impairment since many antihistamines are excreted in the urine in the form of active metabolites.
Promethazine should not be given to neonates and young children owing to their increased susceptibility to antimuscarinic effects.

Adverse reactions
The most common side-effect of Promethazine is CNS depression, with effects varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and incoordination. Others include headache, psychomotor impairment, and antimuscarinic effects, such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation, and increased gastric reflux. Occasional ones include nausea, vomiting, diarrhoea, or epigastric pain, palpitations and arrhythmias. Promethazine may sometimes cause rashes and hypersensitivity reactions (including bronchospasm, angioedema, and anaphylaxis) and cross-sensitivity to related drugs may occur. Photosensitivity can be a problem with promethazine.
Blood disorders, including agranulocytosis, leucopenia, haemolytic anaemia, and thrombocytopenia, although rare, have been reported. Jaundice has also been observed. Other adverse effects that have been reported with promethazine include convulsions, sweating, myalgia, paraesthesias, extrapyramidal effects, tremor, sleep disturbances, depression, confusion, tinnitus, hypotension, and hair loss.

Interactions
Promethazine may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics. Promethazine has an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs). It has been suggested that some sedating antihistamines could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics. Antihistamines may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

Administration and dosage
The following doses of promethazine hydrochloride have been given by mouth.
Adults:
Allergic conditions: 25 mg at night increased to 25 mg twice daily if necessary or
alternatively 10 to 20 mg two or three times daily.
Short-term management of insomnia: 20 to 50 mg at night.
Prevention of motion sickness: 20 or 25 mg the night before travelling followed by a similar dose the following morning if necessary.
Nausea and vomiting arising from causes such as labyrinthitis: 25 mg at night which may be increased to 50 or 75 mg at night or to 25 mg two or three times daily if necessary to a maximum of 100 mg daily.
For severe vomiting in pregnancy, a dose of 25 mg at night, increased if necessary to a maximum of 100 mg is recommended.
Children:
Allergic conditions: 2 to 5 years, 5 to 15 mg daily in one or two divided doses; 5 to 10 years, 10 to 25 mg daily in one or two divided doses.
Night sedation or premedication: 2 to 5 years, 15 to 20 mg; 5 to 10 years, 20 to 25 mg.
Prevention of motion sickness: 2 to 5 years, 5 mg; 5 to 10 years, 10 mg given the night before the journey and repeated on the following morning if necessary.
Promethazine hydrochloride is given parenterally by deep intramuscular injection as a solution of 25 or 50 mg/mL. It may also be given by slow intravenous injection or injected into the tubing of a freely running infusion in a concentration of not more than 25 mg/mL, although it is usually diluted to 2.5 mg/mL. The rate of infusion should not exceed 25 mg/minute. The usual parenteral dose for all indications apart from nausea and vomiting is 25 to 50 mg; a dose of 100 mg should not be exceeded. Doses of 12.5 to 25 mg, repeated at intervals of not less than 4 hours, may be given for the treatment of nausea and vomiting, although not more than 100 mg is usually given in 24 hours.
Children aged 5 to 10 years may be given 6.25 to 12.5 mg of promethazine hydrochloride by deep intramuscular injection.

Distribution Category: POM

Presentation
Tablets:HDPE Jar containing 1000 tablets.
10x10's blister pack.
Syrup: 60 and 100 ml bottles.
Injectable: 1 ml Ampoules.

Storage
Store below 30°C. Protect from light.
Keep out of reach of children.

Manufactured in Kenya by:

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