



AXCEL
PROMETHAZINE-5
SYRUP

COMPOSITION:

Each 5ml contains
Promethazine Hydrochloride 5mg

Sodium Benzoate 0.1% w/v as preservative.

PRESENTATION:

Brown color syrup with sarsi flavor.

INDICATIONS:

It is indicated in the symptomatic relief of allergy or hypersensitivity reactions such as hay fever, urticaria, angioedema, rhinitis, conjunctivitis and pruritic skin disorders; night sedation, treatment and prevention of motion sickness; vertigo of various causes.

PHARMACOLOGY:

Mechanism of Action:

Promethazine Hydrochloride is a Histamine H1-receptor antagonist. The antihistamine acts by competing with histamine for H1 receptor sites on the effector cells, to the exclusion of agonist molecules, without itself initiating a response. This antagonism is competitive and reversible. It does not prevent the production of histamines.

Pharmacokinetics:

Promethazine Hydrochloride is readily absorbed from gastrointestinal tract and parenteral sites of administration. Systemic availability is however affected by high first pass metabolism in the liver. It is highly bound to plasma protein, thus widely distributed throughout the body including the CNS. As it crosses the placenta, amount may be detected in breast milk. Metabolism is extensive. Most of promethazine is slowly excreted as metabolites, through urine and bile. It has elimination half-life of within 5 to 14 hours.

DOSAGE & ADMINISTRATION:

For oral administration only.

For allergic conditions:

Children 2 - 5 years: single dose at night 5ml - 15ml (5mg - 15mg) or 5ml (5mg) two times daily (max. 15ml (15mg) daily).

Children 6 - 12 years: single dose at night 10ml - 25ml (10mg - 25mg) or 5ml - 10ml (5mg - 10mg) two times daily (max. 25ml (25mg) daily).

Adults: 10ml (10mg) two times daily. This may be increased to 20ml (20mg) three times daily if necessary.

For nausea and vomiting:

Children 2 - 5 years: 5ml (5mg) every 4 - 6 hours (max. 15ml (15mg) daily).

Children 6 - 12 years: 10ml (10mg) every 4 - 6 hours (max. 25ml (25mg) daily).

Adults: 25ml (25mg) every 4 - 6 hours (max. 100ml (100mg) daily).

For travel sickness (the night before travel and repeated after 6 - 8 hours if required):

Children 2 - 5 years: 5ml (5mg).

Children 6 - 12 years: 10ml (10mg).

Adults: 25ml (25mg).

CONTRAINDICATION:

Promethazine Hydrochloride should not be used in patients who are in coma or suffering from CNS depression of any cause. It must not be given to neonates, premature infants or patients hypersensitive to phenothiazines. The product is contraindicated in patients hypersensitive to propylene glycol. Promethazine should be avoided in patients who have been taking MAOIs within the 14 days.

PRECAUTION:

May cause drowsiness and hence impair ability to drive vehicles or operate machinery. Use with caution in pregnancy, nursing mothers, and in patients with narrow angle glaucoma, hyperthyroidism, cardiovascular disease, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction and bladder neck obstruction.

WARNING:

This preparation contains Sodium Metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites. This product contains Promethazine Hydrochloride. It should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression. Unsuitable for phenylketonurics.

SIDE EFFECTS:

The most common effect is sedation, varying from drowsiness to deep sleep, and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness, and incoordination. Sedative effects, when they occur, may diminish after a few days. Other side effects include gastrointestinal disturbances, such as nausea, vomiting, diarrhoea or constipation, colic and epigastric pain. It may also produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest, tingling, heaviness and weakness of the hands. It may potentiate other CNS depressant compound. Large doses may precipitate fits in epileptics.

DRUG INTERACTIONS:

MAO inhibitors may enhance the antimuscarinic effects of promethazine while CNS depressants including alcohol,

barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers may enhance the sedative effects. It is also important to note that promethazine may mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.

OVERDOSAGE & TREATMENT:

Symptoms of overdosage may vary from CNS depression including sedation, cardiovascular collapse, and stimulation including insomnia, hallucination, tremors or convulsion. Other symptoms include dizziness, tinnitus, ataxia, blurred vision and hypotension. If the drug has been taken recently by mouth, the stomach should be emptied by aspiration and lavage. Emetics are generally of little value. The patient should be kept quiet to minimise the excitation which occurs particularly in children. Convulsion and marked CNS stimulation should preferably be treated with diazepam or phenobarbitone intramuscularly; paraldehyde, thiopentone sodium, and chlorpromazine have also been recommended. Severe hypotension may require fluid replacement, and assisted respiration may be necessary. Forced diuresis is of little value since antihistamine are rapidly metabolised and only traces are recovered in the urine.

STORAGE:

Keep container well closed. Store below 30°C. Protect from light.

**KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK**

PACK QUANTITIES:

Available in 60ml & 100ml PET bottle, 120ml amber glass bottle.

Further information can be obtained from pharmacist, physician or the manufacturer.

MAL20020811AZ

Manufacturer and Product Holder :



Kotra Pharma (M) Sdn. Bhd.
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