PROME 5MG/5ML SYRUP

PROME 10MG/5ML SYRUP

COMPOSITION

Prome 5mg/5m1 Syrup:
Each 5 mL contains 5 mg Promethazine hydrochloride and 7.5 mg Methylparaben as preservative.
Prome 10mg/5m1 Syrup:
Each 5 mL contains 10 mg Promethazine hydrochloride and 7.5 mg Methylparaben as preservative.

PRODUCT DESCRIPTION

Light brown coloured, clear syrup with raspberry flavour.

ACTIONS

Promethazine is a long acting antihistamine with a mild atropine-like anticholinergic effect and because of its marked effect on the central nervous system, is of great value as an antiemetic, hypnotic, tranquilizer, a potentiator of anaesthetic, hypnotics, sedatives and analgesics.

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.

INDICATIONS

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:

- For sedation and treatment of insomnia inadults. - As a paediatric sedative.

CONTRAINDICATIONS

Prome is contraindicated in those who are hypersensitive to promethazine or to any of the excipients. Prome should not be used in patients in coma or suffering from CNS depression of any cause. It should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

WARNINGS

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.

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.

Promethazine may cause marked drowsiness. Ambulatory patients should be cautioned against such activities as driving or operating dangerous machinery until it is known that they do not become drowsy or dizzy from promethazine therapy.

The sedative action of promethazine hydrochloride is additive to the sedative effects of central nervous system depressants; therefore, agents such as alcohol, narcotic analgesics, sedatives, hypnotics, and tranquilizers should either be eliminated or given in reduced dosage in the presence of promethazine hydrochloride. When given concomitantly with promethazine hydrochloride, the dose of barbiturates should be reduced by at least one-half, and the dose of an analgesic depressants, such as morphine or meperidine, should be reduced by one-quarter to one half.

Promethazine may lower seizure threshold. This should be taken into consideration when administering to persons with known seizure disorders or when giving in combination with narcotics or local anesthetics which may also affect seizure threshold.

Sedative drugs or CNS depressants should be avoided in patients with a history of sleep apnea.

Antihistamines should be used with caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, and urinary bladder obstruction due to symptomatic prostatic hypertrophy and narrowing of the bladder neck.

Administration of promethazine has been associated with reported cholestatic jaundice.

PREGNANCY AND LACTATION

The use of promethazine syrup is not recommended in the two weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Promethazine syrup should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Available evidence suggests that the amount excreted in human milk is insignificant.

DRUG INTERACTIONS

The sedative action of promethazine is additive to the sedative effects of the other central nervous system depressants, including alcohol, narcotic analgesics, sedatives, hypnotics, tricyclic antidepressants, and tranquilizers; therefore, these agents should be avoided or administered in reduced dosage to patients receiving promethazine.

ADVERSE REACTIONS

Promethazine is generally well tolerated. Daytime drowsiness, when present, usually responds to dosage adjustment. For those in charge of vehicles or machinery, or already using sedatives and hypnotics initial doses should be low. Rare side effects include dizziness, slight disorientation, mild headache, twitching of the limbs at night, ataxia and nightmares.

ROUTE OF ADMINISTRATION:

Oral administration

DOSAGE AND ADMINISTRATION

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

As an antihistamine in allergy:
Children 2-5 years : Either 5 - 15 mg as a single dose OR 5 mg bd.
Maximum daily dose 15 mg.
Children 5-10 years : Either 10 - 25 mg as a single dose OR 5 - 10 mg bd.
Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly) : Initially 10 mg bd.
Increasing to a maximum of 20 mg tds as required.

As an antiemetic:
Children 2-5 years : 5 mg to be taken the night before the journey.
To be repeated after 6 - 8 hours as required.
Children 5-10 years : 10 mg to be taken the night before the journey.
To be repeated after 6 - 8 hours as required.
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.

Short term sedation:
Children 2-5 years : 15 or 20 mg as a single night time dose.
Children 5-10 years : 20 or 25 mg as a single night time dose.
Children over 10 years and adults (including elderly) : 25 or 50 mg as a single night time dose.
The use of Promethazine hydrochloride syrup to provide these doses is recommended.

OVERDOSAGE

Symptoms: The chief sign of acute poisoning from ingestion of an overdose of promethazine is unconsciousness which is, however, commonly delayed. In addition, convulsions, hallucinations, delirium, acute anxiety, extreme hyperaesthesia and hyperalgesia with extensor plantar responses may occur. Anticholinergic action may cause tachycardia, flushed skin, dry mouth and sometimes mydriasis.

Treatment: An immediate first aid measure is to induce vomiting mechanically, or to give an emetic, the value of which, however, is limited by the antiemetic activity of promethazine once absorbed. The most important step in the treatment must be, therefore, to remove as much as possible of the unabsorbed material by means of gastric lavage with warm sodium bicarbonate solution. Some of the solution should be left in the stomach to precipitate insoluble promethazine base, thus delaying its absorption.

For acute anxiety, hallucination and convulsions some form of sedation is required, chlorpromazine is the drug of choice because of its recognized value in hallucinated and disturbed patients; 0.5 to 1 mg per kg boayweight would be a suitable dose of chlorpromazine for sedation.

Inhalation of oxygen and carbon dioxide may be necessary if early signs of respiratory failure appears, and the administration of penicillin or another antibiotic as a prophylactic against pneumonia should be considered.

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.

CONDITIONS

Store below 30°C
Keep container tightly closed.
Protect from light.
Keep out of reach of children.
Jauhi dari kanak-kanak.

PRESENTATION

Bottles of 120 ml and 60m1.

MANUFACTURED BY

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DATE OF REVISION

August 2021