PROMETHAVARD-25TABLETS
(Vardhman Exports),

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PROMETHAVARD-25 TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Sugar coated tablet contains:

Promethazine Hydrochloride BP 25 mg

Excipients with known effects:

Each tablet contains 16.71 mg of Dibasic Calcium Phosphate.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Blue coloured, circular, biconvex sugar coated tablets with "PROMETHA 25"Printed with black ink on one side of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Promethavard 25 Tablet is indicated in 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 antiemetic.

For short term use:

Treatment of insomnia in adults.

For short term use as a paediatric sedative.

4.2 Posology and method of administration

Posology:

Not for use in children under the age of 2 years (see section 4.3).

As an antihistamine in allergy:

Children 2-5 years	The use of Phenergan Elixir is recommended for this age group.
Children 5-10 years	25 mg as a single dose*. Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly)	25 mg as a single dose*. Increasing to a maximum of 25 mg bd as required.

*Single doses are best taken at night.

As an antiemetic:

Children 2-5 years	The use of Phenergan Elixir is recommended for this age group.
Children 5-10 years	The use of Phenergan Elixir or Phenergan 10 mg Tablets is recommended.
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.

As a paediatric sedative for short term use and for short term treatment of insomnia in adults:

Children 2-5 years	The use of Phenergan Elixir is recommended for this age group.
Children 5-10 years	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.

Method of Administration

Tablets should be swallowed whole with adequate fluids (at least 100ml of water) and should be taken in an upright sitting or standing position

4.3 Contraindications

Promethavard 25 Tablet should not be used in patients in coma or suffering from CNS depression of any cause.

Promethavard 25 Tablet should not be given to patients with a known hypersensitivity to promethazine or to any of the excipients.

Promethazine is contraindicated for use in children less than two years of age because of the potential for fatal respiratory depression..

Promethavard 25 Tablet should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.4 Special warnings and precautions for use

Promethavard 25 Tablet 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 pyloro-duodenal obstruction.

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

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.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Promethavard 25 Tablet should not be used for longer than 7 days without seeking medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Promethavard 25 Tablet will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment.
Promethavard 25 Tablet may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results.
Promethavard 25 Tablet should be discontinued at least 72 hours before the start of skin tests as it may inhibit the cutaneous histamine response thus producing false-negative results.

4.6. Fertility, Pregnancy and lactation

Promethavard 25 Tablet should not be used in pregnancy unless the physician considers it essential. The use of Promethavard 25 Tablet is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonatal irritability and excitement.

4.7 Effects on ability to drive and use machines

Because the duration of action may be up to 12 hours, patients should be advised that if they feel drowsy they should not drive or operate heavy machinery.

4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 00 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from the available data).

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. 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 urticaria, rash, pruritus, anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, restless legs syndrome, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

<u>Reporting of suspected adverse reactions</u>

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Symptoms of severe overdosage 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. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antihistamines for systemic use; Phenothiazine derivatives,

ATC code: R06AD02

Potent, long acting, antihistamine with additional anti-emetic central sedative and anti-cholinergic properties.

5.2 Pharmacokinetic properties

Promethazine is distributed widely in the body. It enters the brain and crosses the placenta. Promethazine is slowly excreted via urine and bile. Phenothiazine pass into the milk at low concentrations.

5.3 Preclinical safety data

Non-Clinical data reveal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic Calcium Phosphate,
Bleach shellac,
Maize Starch,
Methyl Paraben,
Propyl Paraben,
Purified Talc,
Bleach shellac,
Calcium Carbonate Heavy,
Kaolin,
Gelatin,
Sugar,
Gum Accecia,
Titanium dioxide,
Colour Brilliant Blue ,
Carnuaba wax.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a cool place and protect from light. Keep all medicines out of reach of children.

6.5 Nature and contents of container

1000 tablets are sealed in PP bag printed with VARDHMAN packed in a 200ml white plastic container sealed with white cap having two silica bags and a literature.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

NAME & ADDRESS:

VARDHMAN EXPORTS

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