Summary product characteristics:

1. Name of the medicinal product

Dawa-prom tablets.

2. Qualitative and quantitative composition

Each film coated tablet contains: Promethazine hydrochloride BP 25mg.

For the full list of excipients, see section 6.1

3. Pharmaceutical form: Film coated tablet

Blue coloured,round,biconvex film coated tablets pain on both sides

4. Clinical particulars

4.1 Therapeutic 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 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

Route of administration: Oral.

Not for use in children under the age of 2 years.

As an antihistamine in allergy:

Children 2-5 years	The use of Dawa-prom syrup 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 Dawa-prom is recommended for this age group.
Children 5-10 years	The use of Dawa-prom 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 Dawa-prom 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.

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4.3 Contraindications.

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

Promethazine 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.

Promethazine should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously

4.4 Special warnings and precautions for use.

Promethazine 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, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Phenergan should not be used for longer than 7 days without seeking medical advice

4.5Interaction with other medicinal products and other forms of interactions:

Promethazine will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Promethazine may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results. Promethazine 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 Pregnancy and Lactation

Promethazine should not be used in pregnancy unless the physician considers it essential. The use of Phenergan 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 the 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 hyper excitability. 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, 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

4.9 Overdose

Symptoms of severe overdosage are variable. They are characterized 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 Pharmacodynamic 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

5.2Pharmacokinetic Properties

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

5.3 Preclinical safety data

No additional preclinical data of relevance to the prescriber

6. Pharmaceutical particulars

6.1 List of excipients

Lactose monohydrate Maize
starch Microcrystalline
cellulose Disodium EDTA
PVP K 30
Purified talc
Magnesium stearate
Hypromellose 6cps
Titanium dioxide
Purified talc Brilliant
blue color
Propylene glycol
Isopropyl alcohol
Dichloromethane
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture

6.4 Special precautions for storage

Store in dry place, below 30^{O}C. Protected from direct sunlight

6.5 Nature and contents of container

Blister packs of 10x10 in printed unit box and bulk packs of 1000's in a well labeled 300cc HDPE jars pack with literature insert

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

Dawa Limited,
Plot No.7879/8 Baba Dogo Road, Ruaraka
P.O Box 16633-00620 Nairobi –Kenya

8. Registration number(s)

Kenya- H2010/21230/187

9. Legal category: Prescription only medicine, **(POM)**

10. Date of revision of the text

January 2023.