Summary of product characteristic

1. Name of the medicinal product

Dawa-prom syrup

2. Qualitative and quantitative composition

Each 5ml contains: Promethazine hydrochloride BP 5mg.

For full list of excipients see section 6.1.

3. Pharmaceutical form

Oral syrup

An orange coloured syrup, free from any visible evidence of contamination.

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	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.

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

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 Dawa-prom tablets to provide these doses is recommended.

4.3 Contraindications

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

Dawa-prom 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.
Dawa-prom 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.
Promethazine should not be used for longer than 7 days without seeking medical advice.
Promethazine contains Maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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 Fertility, pregnancy and lactation

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

The preservatives used in Dawa-prom Elixir have been reported to cause hypersensitivity reactions, characterized by circulatory collapse with CNS depression in certain susceptible individuals with allergic tendencies.

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. Tachycardia may develop. 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.

5.2 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. 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

White refine sugar
Sodium Metabisulphite
Disodium edetate
Sodium methylparaben
Sodium propyl paraben
Bronopol
Natrosol gum
Ascorbic acid
Sodium saccharin
Sunset yellow colour
Orange flavor liquid
Purified water.

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years when unopened. 1 month when opened.

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protected from light.

Keep all medicine out of reach of children.

6.5 Nature and contents of container

A well labeled amber coloured PET bottle of 60ml and 100ml, packed in unit box with literature insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0 Marketing authorisation holder

Dawa Limited,

Plot No 7879/8, Baba Dogo Rd., Ruaraka

P.O Box 16633-00620 Nairobi –Kenya

8.0 Marketing authorisation number(s)

H2008/20105/981

9.0 Date of first authorisation: 7th April 2009

Renewal of the authorisation: Annually.

10.0 Date of revision of the text: May 2016