SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Promethazine Hydrochloride 25mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 25 mg of the active substance promethazine hydrochloride equivalent to 22.15 mg promethazine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
White coloured, oval shaped, 9.8 x 6.2 mm biconvex, film-coated tablets debossed with "C25" on one side and plain on other side.

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.
- As a paediatric sedative.

4.2 Posology and method of administration

Posology

Paediatric population
Promethazine 25 mg film-coated tablets are not recommended for use in children under 6 years.

As an antihistamine in allergy:

Children 6-10 years	25 mg as a single dose*. Maximum daily dose 25 mg.
Children over 10 years and adults (including	25 mg as a single dose*. Increasing to a maximum of 25 mg twice daily as required.

elderly)	

*Single doses are best taken at night.

As an antiemetic:

Children 6-10 years	Promethazine 25 mg film-coated tablets are not suitable for this age group. Other strengths and pharmaceutical forms of promethazine may be available.
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 use as a paediatric sedative:

Children 6-10 years	25 mg as a single night time dose.
Children over 10 years	25 or 50 mg as a single night time dose.

Short term treatment of insomnia in adults:

Adults (including elderly)	25 or 50 mg as a single night time dose.

Method of administration

Oral.

4.3 Contraindications

Promethazine film-coated tablets are contraindicated:
- in patients with hypersensitivity to the active substance, other phenothiazines, or to any of the excipients listed in section 6.1
- in patients in coma or suffering from CNS depression of any cause
- in patients taking monoamine oxidase inhibitors up to 14 days previously

Promethazine is contraindicated for use in children less than six years of age (see section 4.4).

4.4 Special warnings and precautions for use

Hypersensitivity reactions including anaphylaxis, urticaria and angioedema have been reported with Promethazine use. In case of allergic reaction, treatment with Promethazine must be discontinued and appropriate symptomatic treatment initiated (see Section 4.8).

Promethazine should be avoided in patients with liver or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, pheochromocytoma, myasthenia gravis, or prostate hypertrophy, or in patients with a history of narrow angle glaucoma or agranulocytosis.

Caution must be exercised when using H1-antihistamines such as Promethazine due to the risk of sedation. Combined use with other sedative medicinal products is not recommended (see section 4.5).

Caution should be used in patients with:

- asthma, bronchitis or bronchiectasis. Promethazine may thicken or dry lung secretions and impair expectoration.
- severe coronary artery disease
- epilepsy
- bladder neck or pyloro-duodenal obstruction.

As with neuroleptics, Neuroleptic Malignant Syndrome (NMS) characterized by hyperthermia, extrapyramidal disorders, muscle rigidity, altered mental status, autonomic nervous instability and elevated CPK, may occur. As this syndrome is potentially fatal, promethazine must be discontinued immediately and intensive clinical monitoring and symptomatic treatment should be initiated.

Ototoxicity

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.

QT interval

As phenothiazines can prolong the QT interval, caution is advised in treated patients with pronounced bradycardia, cardiovascular disease, with a hereditary form of prolongation of the QT interval and concomitant use with other products leading to QT prolongation.

QT prolongation

Phenothiazine derivatives may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalaemia, and acquired (i.e. drug induced) QT prolongation. If the clinical situation permits, medical and laboratory evaluations should be performed to rule out possible risk factors before initiating treatment with a phenothiazine derivative and as deemed necessary during treatment (see section 4.8).

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

Photosensitivity reactions

Due to the risk of photosensitivity, exposure to strong sunlight or ultraviolet light should be avoided during or shortly after treatment (see section 4.8).

Paediatric population

Promethazine must not be used in children less than six years of age due to the potential for fatal respiratory depression, psychiatric and CNS events (see Section 4.3 and Section 4.8).

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

Alcohol and alcohol-containing medicines should be avoided while on this medicine (see section 4.5).

Phenothiazines may be additive with, or may potentiate the action of, other CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, general anesthetics, or alcohol.

The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8) and requires immediate hematological investigation.

All patients should be advised that, if they experience fever, sore throat or any other infection, they should inform their physician immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes (hyperleucocytosis, granulocytopenia) are observed in the blood count.

Excipients

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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. Combination with alcohol enhances the sedative effects of H1 antihistamines.

Promethazine may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results.

Special caution is required when promethazine is used concurrently with other products leading to QT prolongation, including medicinal products such as antipsychotics, i.e., some phenothiazines (chlorpromazine, levomepromazine), benzamides (sulpiride, amisulpride, tiapride), pimozide, haloperidol, droperidol, citalopram, halofantrin, methadone, pentamidine, and moxifloxacine.

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.

Cytochrome P450 2D6 Metabolism: Some phenothiazines are moderate inhibitors of CYP2D6. There is a possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines, and CYP2D6 substrates. Co administration of promethazine with amitriptyline/amitriptylinoxide, a CYP2D6 substrate, may lead to an increase in the plasma levels of amitriptyline/amitriptylinoxide. Monitor patients for dose-dependent adverse reactions associated with amitriptyline/amitriptylinoxide.

Promethazine should be avoided in patients taking monamine oxidase inhibitors within the previous 14 days, and monamine oxidase inhibitors should be avoided while using Promethazine.

Seizure threshold-lowering drugs: Concomitant use of seizure-inducing drugs or seizure threshold-lowering drugs should be carefully considered due to the severity of the risk for the patient (see section 4.4).

Gastro-intestinal agents that are not absorbed (magnesium, aluminium and calcium salts, oxides and hydroxides): Reduced gastro-intestinal absorption of phenothiazines may occur. Such gastro-intestinal agents should not be taken at the same time as phenothiazines (at least 2 hours apart, if possible).

Drugs with anticholinergic properties: Concomitant use of Promethazine with drugs with anticholinergic properties enhances the anticholinergic effect.

4.6 Fertility, pregnancy and lactation

Pregnancy
The use of Promethazine is not recommended during pregnancy and in women of childbearing potential not using contraception, unless the potential benefits outweigh the potential risks. When promethazine has been given in high doses during late pregnancy, promethazine has caused prolonged neurological disturbances in the infant.

Advise patients to inform their healthcare provider of a known or suspected pregnancy. Advise patients to avoid becoming pregnant while receiving this medicine. Advise female patients of reproductive potential to use effective contraception.

There are no available animal studies regarding reproductive toxicity.

Breast-feeding
Promethazine is excreted in breast milk (see section 5.2). There are risks of neonatal irritability and excitement. Promethazine is not recommended for use in breast-feeding.

Fertility
No data available.

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, dizzy and have blurred vision, 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).

Immune system disorders

Frequency not known: Allergic reactions, including anaphylactic reaction, urticaria, angioedema.

Blood and lymphatic system disorders
Frequency not known: Thrombocytopenia

Psychiatric disorders
Frequency not known: Hallucinations, aggression, agitation, confusional state, anxiety.
Frequency not known: Infants, newborns and premature are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation
Frequency not known: children less than 6 years of age also experienced aggression and hallucination.

Nervous system disorders
Very common: Sedation or somnolence
Common: Drowsiness
Frequency not known: Dizziness, headaches, psychomotor hyperactivity, extrapyramidal effects including restless legs syndrome, muscle spasms and tic-like movements of the head and face, neuroleptic malignant syndrome.
Frequency not known: Dystonia, including oculogyric crisis, usually transitory are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases.
Frequency not known: Anticholinergic effects such as ileus paralytic, risk of urinary retention, dry mouth, constipation, accommodation disorder.
The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine.
Frequency not known: children less than 6 years of age also experienced psychomotor hyperactivity.

Cardiac disorders
Frequency rare: Palpitations, arrhythmias
Frequency not known: QT prolongation, Torsade de pointes

Renal and urinary disorders
Frequency uncommon: Urinary retention

Metabolism and nutrition disorders
Frequency not known: Decreased appetite

Skin and subcutaneous tissue disorders
Frequency uncommon: Rash, photosensitivity reaction

Gastrointestinal disorders
Frequency not known: Epigastric irritation/discomfort, dry mouth

Eye disorders
Frequency not known: Blurred vision

Vascular disorders
Frequency not known: Hypotension

Respiratory, thoracic and mediastinal disorders
Frequency not known: Respiratory depression (see Section 4.4), nasal congestion

Hepatobiliary disorders
Frequency not known: Jaundice cholestatic

Blood and lymphatic system disorders
Frequency very rare: Blood dyscrasias including haemolytic anaemia, agranulocytosis, leukopenia, eosinophilia, thrombocytopenia (including thrombocytopenic purpura).
Frequency not known: Thrombocytopenia

General disorders and administration site conditions
Frequency not known: Tiredness

Reporting of suspected adverse reactions
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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms
Symptoms of severe overdosage are variable. They are characterised in children by various combinations of excitation, ataxia, incoordination, athetosis and hallucinations, intellectual disability and cognition deficit in children less than 6 years of age 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. High doses (supratherapeutic doses) can cause ventricular arrhythmias including QT prolongation and torsade de pointes (see section 4.8).

Management
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.

Prolonged QT interval and cases of severe arrhythmias with fatal outcome have been described in overdose of phenothiazines.

Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or another suitable anticonvulsant.

In the event of overdose of Promethazine, take all appropriate measures immediately.

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

Tablet core:
Microcrystalline cellulose
Calcium hydrogen phosphate dihydrate
Sodium starch glycolate (Type A)
Stearic acid
Magnesium stearate

Tablet Coating:
Hypromellose (E464)
Macrogol 8000 (E1521)
Titanium dioxide (E171)
Talc

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Promethazine 25 mg film-coated tablets are available in blister packs: (White opaque PVC/ ACLAR forming foil and lidding plain push through aluminium foil, PVC/PCTFE/PVC foil or PVC/PVDC/PVC foil and lidding aluminum foil) of 5, 7, 8, 10, 14, 15, 16, 20, 30 and 56 film-coated tablets.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2200

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/06/2016
21/01/2025

10 DATE OF REVISION OF THE TEXT

30/07/2025