SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Promethazine hydrochloride 10 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of the active substance Promethazine hydrochloride

Excipient(s) with known effect:

Also contains 23.68 mg of lactose and 33.7 mg of Sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Sugar-coated tablet

Blue sugar-coated tablets

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:

Not for use in children under the age of 2 years (see section 4.3).
The use of Promethazine liquid is recommended for children aged 2 -5 years.

As an antihistamine in allergy:

Children 5-10 years	Either 10 or 20 mg as a single dose*. Or 10 mg twice a day (bd). Maximum daily dose 20 mg.
Children over 10 years and adults (including elderly)	Initially 10 mg twice a day (bd). Increasing to a maximum of 20 mg three times a day (tds) as required.

*Single doses are best taken at night.

As an antiemetic:

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)	20 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 5-10 years	20 mg as a single night time dose.
Children over 10 years and adults (including elderly)	20 to 50 mg as a single night time dose

Method of administration

Oral

4.3 Contraindications

Promethazine should not be given to patient with a known hypersensitivity to the active substance, promethazine or to any of the excipients listed in section 6.1.

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

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 should not be used for longer than 7 days without seeking medical advice.
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
• Narrow angle glaucoma
• Epilepsy
• Hepatic and renal insufficiency
• Bladder neck or pyloro-duodenal obstruction

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.

QP 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).

Photosensitivity reactions
Due to the risk of photosensitivity, exposure to strong sunlight or ultraviolet light should be avoided during or shortly after treatment.

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

Excipient(s) with known effect
This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency 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. 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.
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.

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.

Special caution is required when promethazine is used concurrently with drugs known to cause QT prolongation (such as antiarrhythmics, antimicrobials, antidepressants, antipsychotics) to avoid exacerbation of risk of QT prolongation.

4.6 Fertility, pregnancy and lactation

Pregnancy

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.

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.

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 (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system disorders
Allergic reactions, including urticaria, rash, pruritus and anaphylactic reactions have been reported.

Skin and subcutaneous tissue disorders
Photosensitive skin reactions have been reported.

Nervous system disorders
Somnolence, dizziness, headaches, extrapyramidal effects, restless legs syndrome, muscle spasms and tic-like movements of the head and face.
The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine.
Not known: neuroleptic malignant syndrome, psychomotor hyperactivity.

Psychiatric disorders
Restlessness, nightmares, and disorientation.
Infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability.
Not known: hallucinations, aggression.

Eye disorders
Blurred vision

Gastrointestinal disorders
Epigastric irritation/discomfort, dry mouth

Renal and urinary disorders
Urinary retention

Metabolism and nutrition disorders
Anorexia

Cardiac disorders
Palpitations, arrhythmias
Not known: QT prolongation ,torsade de pointes

Vascular disorders
Hypotension

Hepatobiliary disorders
Jaundice

Blood and lymphatic system disorders

Blood dyscrasias including haemolytic anaemia rarely occur. Agranulocytosis. Not known: thrombocytopenia.

General and administration site conditions
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 at: 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, inco-ordination, 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.
High doses (supratherapeutic doses) can cause ventricular arrhythmias including QT prolongation and torsade de pointes (see section 4.8).

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

Management
If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the anti-emetic 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

Lactose

Maize Starch

Pregelatinised Maize Starch

Magnesium Stearate

Bleached Shellac

Talc

Talc, purified

Titanium Dioxide

Polyvinylpyrrolidone K25

Opalux Blue AS-F-4321G

Sucrose

Beeswax

Carnauba Wax

6.2 Incompatibilities

Promethazine Hydrochloride is incompatible with alkaline substances which precipitate Promethazine Base.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 25°C**.** Store in the original packaging. Keep the blister packs in the outer carton.

6.5 Nature and contents of container

Blister of 250 micron PVC and 20 micron aluminium foil, with 5/6 gsm heat-seal lacquer on the dull side and printed on the bright side. Pack sizes: 16 and 56.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0134

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10 DATE OF REVISION OF THE TEXT

10/03/2025