SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Promethazine Hydrochloride 10mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg of Promethazine hydrochloride.
Excipient with known effect
Each tablet contains 71.600mg of lactose monohydrate.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Round, pale blue colored, biconvex, bevelled edge film 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

Route of administration: Oral.

Paediatric population

Not for use in children under the age of 2 years (see section 4.3). The use of Promethazine Hydrochloride 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. Maximum daily dose 20 mg.
Children over 10 years and adults (including elderly)	Initially 10 mg bd. Increasing to a maximum of 20 mg three times a day 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 insomniain 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.

4.3 Contraindications

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

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

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

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

4.4 Special warnings and precautions for use

Promethazine Hydrochloride 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 hydrochloride 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.

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.

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 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 aftertreatment.

Paediatric population

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

Excipient(s) with known effect
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take thismedicine.

4.5 Interaction with other medicinal products and other forms of interaction

Promethazine hydrochloride 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 H1antihistamines.

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

Promethazine hydrochloride 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.

4.6 Fertility, pregnancy and lactation

Pregnancy

Promethazine Hydrochloride should not be used in pregnancy unless the physician considers it essential. The use of Promethazine hydrochloride is not
recommended in the 2 weeks prior to delivery in view of the risk of irritabilityand excitement in the neonate.

Breast-feeding

Promethazine Hydrochloride is excreted in breast milk (see section 5.2)There are risks of neonatal irritability and excitement. Promethazine Hydrochloride 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 (≥1/1000 to <1/100); rare (≥1/10 00 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from theavailable 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.

Frequency “not known”: *neuroleptic malignant syndrome, psychomotor hyperactivity*

The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine.

Psychiatric disorders
Restlessness, nightmares, and disorientation.
Frequency “not known”: hallucinations, aggression

Infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability.

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 (including QT prolongation and torsade de pointes)
Frequency “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.
Frequency “not known”: thrombocytopenia

General and administration site conditions
Tiredness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinalproduct 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Cardin the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Symptoms of severe overdosage are variable.

Prolonged QT interval and cases of severe arrhythmias with fatal outcome have

been described in overdose of phenothiazines.

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. 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 ofpromethazine; 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 another suitable anticonvulsant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anthihistamines for systemic use; Phenothiazine derivatives, ATC code: R06AD02.

Promethazine Hydrochloride is a potent, long acting, antihistamine with additional anti-emetic, central sedative properties 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 monohydrate

Maize starch

Povidone K30

Magnesium stearate

Colourant: Opadry 03F505142 Blue

Titanium dioxide (E 171)

Hypromellose (E464)

Macrogol/Polyethylene glycol (E1521)

Indigo carmine aluminium lake FD&C Blue no 2 (E132)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30^{o}C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

White opaque PVC-PVDC 250 microns/20 microns Aluminium foil coated with VMCH in blister packs of 28, 56, 84 and 100 tablets.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Noumed Life Sciences Limited
Noumed House, Shoppenhangers Road,
Maidenhead, Berkshire, SL6 2RB, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 44041/0170

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/08/2025

10 DATE OF REVISION OF THE TEXT

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