SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Phenergan Night Time 25 mg Film-coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect:
Also contains 173.52 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets (tablets)

Pale blue film coated tablets marked PN 25 on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For short term use in the treatment of insomnia in adults and as a sedative in children over 16 years of age.

4.2 Posology and method of administration

Adults (including the elderly) and children over 16 years of age: 25 mg or 50 mg as a single night time dose.

Paediatric population: Not to be used in children under 16 years of age.

Method of administration
For oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Phenergan Night Time should not be used in patients in coma or suffering from CNS depression of any cause.
Phenergan Night Time should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.4 Special warnings and precautions for use

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

Caution should be used in patients with:

- Asthma, bronchitis or bronchiectasis. Phenergan Night Time 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 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 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

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Phenergan Night Time 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.

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

Phenergan Night Time 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 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
Phenergan Night Time should not be used in pregnancy unless the physician considers it essential. The use of Phenergan Night Time is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Breast-feeding
Phenergan is excreted in breast milk (see section 5.2). There are risks of neonatal irritability and excitement. Phenergan 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 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.

Psychiatric disorders
Restlessness, nightmares and disorientation.

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)

Vascular disorders
Hypotension

Hepatobiliary disorders
Jaundice

Blood and lymphatic system disorders
Blood dyscrasias including haemolytic anaemia rarely occur. Agranulocytosis.

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 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, 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 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 another 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

There are no preclinical data of relevance to the prescriber, which are additional to any already included in other sections of the SmPC,

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Povidone K30
Magnesium stearate
Polyethylene glycol 200
Hypromellose (Pharmacoat 606)

Colouring agent: Opaspray M-1-4210A
Titanium dioxide (E171)
Hypromellose (E464)
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 carton in order to protect from light.

6.5 Nature and contents of container

Opaque white 250µm uPVC coated with 40gsm PVdC. 20µm hard temper aluminium foil (coated with vinyl heat seal lacquer).
Pack size: 14 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare UK Limited, trading as Sanofi
410 Thames Valley Park Drive,
Reading,
Berkshire,
RG6 1PT,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 53886/0058

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/01/2025

10 DATE OF REVISION OF THE TEXT

31/01/2025