Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Phenergan 5 mg/5 ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml spoonful contains Promethazine Hydrochloride 5 mg

Excipients with known effect
Contains Sodium Sulphite (E221) 5.0 mg, Sodium Citrate 140.0 mg, Sodium Metabisulphite (E223) 5.0 mg, Sodium Benzoate (E211) 5.0 mg, Maltitol Liquid 4.44 g, Ethanol 0.03 mg in each 5 ml
Sodium content is 37 mg/5 ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

A clear bright golden oral solution with an odour of oranges.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In the treatment of allergic conditions and reactions.
As an antiemetic.

4.2 Posology and method of administration

Route of administration: Oral

Not for use in children under the age of 2.

Adults: The usual daily dose is 25-75mg as a single daily dose or in 3 divided doses, starting with the lower dose.

Children: Children 2-5 years:
1-3 x 5ml spoonfuls (5-15mg) once daily at bedtime
Or 5mg twice daily
Maximum daily dose 15mg

Children 5-10 years:
2-5 x 5ml spoonfuls (10-25mg) once daily at bedtime
Or 5-10mg twice daily
Maximum daily dose 25mg

When two doses are required in 24 hours, the lower dose should be used.

4.3 Contraindications

Phenergan should not be used in patients in pre-coma states, in a coma or suffering from CNS depression of any cause.

It must not be given to neonates, or premature infants.

Phenergan should not be given to patients with a known hypersensitivity to promethazine or to any of the excipients.

Phenergan should be avoided in patients with blood dycrasias and in patients taking monoamine oxidase inhibitors up to 14 days previously.

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

4.4 Special warnings and precautions for use

Caution should be used in patients with pre-existing coronary insufficiency. Adjustment of dosage may be necessary to avoid postural hypotension, especially in the elderly.
Since the drug is metabolized in the liver, promethazine should be used cautiously in patients with hepatic impairment.

Prolonged treatment with this product may result in jaundice or blood dyscrasia necessitating regular monitoring of liver function and haemopoietic state.

Particular attention should also be paid to potential for inducing eye changes and myocardial conduction defects, especially if other concurrently administered drugs also have potential effects on these systems.

Due to the risk of photosensitivity, exposure to the sun or ultraviolet light should be avoided during or shortly after treatment.

Body temperature may fall during treatment with this product and special care should be exercised in this regard in the elderly.

Promoethazine should only be used cautiously in epileptic patients, since central nervous stimulation may sometimes occur. Caution should also be exercised in patients with narrow angle glaucoma, renal insufficiency, bladder-neck or pyloro-duodenal obstruction.

Promethazine may thicken or dry lung secretions and impair expectoration. It should be used with caution in patients with asthma, bronchitis or bronchiectasis.

Promethazine may delay the elderly diagnosis of intestinal obstruction or increased intracanial pressure through the suppression of vomiting.

Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs e.g. salicylates.

There have been case reports of drug abuse with promethiazine. The risk of abuse is greater in patients with a history of drug abuse.

Neuroleptic malignant syndrome: 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, promethiazine must be discontinued immediately and intensive clinical monitoring and symptomatic treatment should be initiated.

Promethiazine must not be used in children below two years of age due to the potential for fatal respiratory depression.

Phenothiazines should be used with caution in patients with cardiac disease or cardiac arrhythmias.

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

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

Excipients
This medicinal product contains 37 mg sodium per 5 ml, equivalent to 1.9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
This medicinal product contains 0.03 mg of ethanol in each 5 ml which is equivalent to 0.006 mg/ml. The amount in 5 ml of this medicinal product is equivalent to less than 1 ml beer or 1 ml wine.
The small amount of ethanol in this medicinal product will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

The product may potentiate the effects of alcohol and other central nervous system depressants. Alcohol should be avoided during treatment.

Attention is drawn to the fact that many psychotropic and anti-histamine drugs are of the phenothiazine group, and a combination of both may lead to toxicity. Potentiation of action may also occur with monoamine oxidase inhibitors and analgesics. Use of promethazine should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously. Antihypertensive therapy used concurrently may need adjustment of dosage to avoid hypotension, particularly in the elderly.

Phenergan will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic.

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

Phenergan should be discontinued at least 72 hours before commencing skin tests using allergen extracts, as the cutaneous histamine response may be inhibited.

Promethazine may lower the convulsion threshold. Dosage adjustment of anticonvulsant medication may be necessary.

Concurrent use of promethazine with other hepatotoxic medications may increase the potential for hepatotoxicity.

Concurrent use with other photosensitizing medications, e.g. tetracyclines, may cause additive photosensitizing effects.

4.6 Fertility, pregnancy and lactation

Promethiazine should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.

When promethiazine has been given in high doses during late pregnancy, promethiazine has caused prolonged neurological disturbances in the infant.

The use of Phenergan is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Phenergan is excreted in breastmilk. There are riks of neonatal irritability and excitement. Phenergan is not recommended for use in breastfeeding.

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 isused, when applicable:
Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1and <1%; Rare ≥ 0.01 and <0.1%; Very rare <0.01%; Not known (cannot be estimated from available data).

Immune System Disorders
Frequency unknown: Allergic reactions, including urticaria, rash, pruritus, and anaphylactic reaction have been reported.

Skin and Subcutaneous Tissue Disorders
Frequency unknown: Photosensitivity reaction

Nervous System Disorders
Frequency unknown: Neuroleptic Malignant Syndrome, the elderly are particularly susceptible to the anticholinergic effects and confusion due to Phenergan, somnolence, dizziness, headaches, extrapyramidal effects including muscle spasm, tic-like movements of the head and face (akathisia, dystonia, tardive dyskinesia) especially in the presence of pre-existing brain damage.

Metabolism and Nutrition Disorders
Frequency unknown: Anorexia

Gastrointestinal Disorders
Frequency unknown: Epigastric discomfort, dry mouth

Eye Disorders
Frequency unknown: Blurred vision

Blood and Lymphatic System Disorders
Frequency unknown: Blood dyscrasias including haemolytic anaemia, agranulocytosis, thrombocytopenia (including thrombocytopenic purpura), eosinophilia

Renal and Urinary Disorders
Frequency unknown: Urinary retention

Psychiatric Disorders
Frequency unknown: Infants, newborns and premature are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation

Cardiac Disorders
Frequency unknown: Palpitations, arrhythmias.

The effects of pheonthiazines on the heart are dose related. ECG changes, with prolongation of QT interval and T-wave changes have been reported commonly in patients treated with moderate or high dose; they are reversible on reducing the dose. In a very small percentage of cases they have been reported to precede serious arrhythmias, including ventricular tachycardia and fibrillation, which have also occurred after overdosage. Sudden, unexpected and unexplained deaths have been reported in patients receiving phenothiazines

Vascular disorders
Frequency unknown: Hypotension

Hepatobiliary disorders
Frequency unknown: Jaundice

General Disorders and Administration Site Conditions
Frequency unknown: 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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

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. 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

Potent, long acting, antihistamine with additional anti-emetic central sedative and anticholinergic 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 pre-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol, liquid
Citric acid (E330)
Sodium citrate
Ascorbic acid
Sodium sulphite anhydrous (E221)
Sodium benzoate (E211)
Orange juice flavour 510844E (contains ethanol)
Caramel HT (E150)
Acesulfame potassium (E590)
Purified water
Sodium metabisulphite (E223)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years

Use within 1 month of opening bottle.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from light.

6.5 Nature and contents of container

100ml Amber glass type III bottle closed with a rolled on, pilfer proof aluminium cap and a PVDC emulsion coated wad or a child proof cap with a seal containing polyvinylidene chloride packed in an outer box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare, France SAS, 157 avenue Charles de Gaulle, 92200 Neuilly-sur-Seine, France

8 MARKETING AUTHORISATION NUMBER

PA23180/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1979

Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

May 2024