

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Phenergan 2.5% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml ampoule contains Promethazine Hydrochloride 25 mg.

Excipients: Contains Sodium Sulphite (E221) 0.5mg and Sodium Metabisulphite (E223) 0.7mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection

Clear, bright, almost colourless, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Route of administration: Intramuscular or Intravenous.

Intramuscular:

Adults:

The usual daily dose is 25-50 mg by deep intramuscular injection. A maximum dose of 100mg parenterally should not be exceeded.

Children:

Children 5-10 years only:

6.25 - 12.5 mg daily by deep intramuscular injection.

Elderly:

No specific dosage recommendations.

Intravenous:

Adults Only:

In an emergency, the usual dose is 25-50mg after dilution to 10 times the volume with water for injection. A maximum dose of 100mg parenterally should not be exceeded.

Elderly:

No specific dosage recommendations.

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 dyscrasias 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

During intravenous administration extreme care must be taken to avoid perivascular extravasation or accidental intra-arterial injection, to avoid severe chemical irritation.

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.

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

Promethazine 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 intracranial 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 promethazine. 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, promethazine must be discontinued immediately and intensive clinical monitoring and symptomatic treatment should be initiated.

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

Intravenous injection should be performed with extreme care to avoid extravasation or inadvertent intra-arterial injection, which could lead to necrosis and peripheral gangrene. If a patient complains of pain during intravenous injection, stop the injection immediately as this may be a sign of extravasation or inadvertent intra-arterial injection. Intramuscular injection must also be performed carefully to avoid inadvertent subcutaneous injection, which could lead to necrosis.

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.

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.

Promethazine may interfere with immunological urine pregnancy tests.

Promethazine 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 photosensitising medications, e.g. tetracyclines, may cause additive photosensitising effects.

Phenergan injection may increase glucose intolerance.

4.6 Fertility, pregnancy and lactation

Phenergan should not be used in pregnancy unless the physician considers it essential. 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.

Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonatal irritability and excitement.

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 side effects have been observed: drowsiness, dizziness, headache, restlessness, tiredness and nightmares. Anticholinergic side effects such as blurred vision, dry mouth and urinary retention occur occasionally. Use of this product at high (relative or absolute) doses may induce extra pyramidal side effects e.g. dyskinesia, akathisia, dystonia, especially in the presence of pre-existing brain damage. These are likely to be particularly severe in children. Children may also display paradoxical hyperexcitability.

Prolonged administration of this product may result in persistent or tardive dyskinesias particularly in the elderly. Other side effects in the elderly include anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, muscle spasms and tic-like movements of the head and face.

Anaphylaxis, jaundice and blood dyscrasia's including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

Frequency unknown: Neuroleptic Malignant Syndrome.

Very rare cases of allergic reactions including urticaria, rash and pruritus have been reported.

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

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 may precede their occurrence. Tachycardia may develop. Cardiorespiratory depression is not 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

Sodium sulphite, anhydrous (E221)
Sodium metabisulphite (E223)
Water for injections

6.2 Incompatibilities

In the absence of compatability studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in the original container in order to protect from light.

6.5 Nature and contents of container

Aluminium/PVC blister tray in an outer box containing white, clear glass (Type I, Ph. Eur.) ampoules.

10 glass ampoules per tray.

Pack size: 10 x 1ml ampoule

10 x 2ml ampoule (each ampoule contains 1 ml of phenergan solution for injection 2.5% w/v).

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

Discoloured solutions should not be used. After opening the ampoule, the solution should be used immediately. Any solution remaining should be discarded.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 540/121/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2009

10 DATE OF REVISION OF THE TEXT

September 2015