SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Phenergan 50 mg/2 ml Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains 56.4 mg/2 ml of the active substance promethazine hydrochloride, equivalent to 50 mg promethazine base.

Excipient(s) with known effect: potassium metabisulfite and sodium sulfite.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Phenergan 50 mg/2 ml is a clear solution.

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.

Sedation and treatment of insomnia in adults.

As an adjunct in preoperative sedation in surgery and obstetrics.

As a paediatric sedative.

Prevention and control of nausea and vomiting associated with certain types of anaesthesia and surgery.

4.2 Posology and method of administration

Route of administration: Intramuscular or intravenous (after dilution)

The usual dose is 25-50 mg by deep intramuscular injection, or, in emergency, by slow intravenous injection after dilution of the 2.5% solution to 10 times its volume with sodium chloride 0.9% immediately before use.

Maximum parenteral dose 100 mg.

Elderly: No specific dosage recommendations.

Children: 6.25-12.5 mg for children from 5-10 years by deep intramuscular injection. Not for use in children under 2 years of age (see section 4.3).

For the treatment of nausea/vomiting

Intramuscular or intravenous dosage:

Adults: 12.5–25 mg every 4-6 hours as needed.
Children ≥ 2 years: 0.25-0.5 mg/kg (max: 25 mg/dose) every 4-6 hours as needed.

4.3 Contraindications

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

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

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

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

4.4 Special warnings and precautions for use

Phenergan may thicken or dry lung secretions and impair expectoration. It should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis.
Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency.

Caution should be exercised in patients with bladder neck or pyloro-duodenal obstruction.

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

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.

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 local necrosis.

Phenergan contains sodium sulfite and potassium metabisulfite and may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

Phenergan will enhance the action of any anticholinergic agent, tricyclic anti-depressant, sedative or hypnotic. Alcohol should be avoided during treatment. Phenergan may cause hypotension, and dosage adjustment of antihypertensive

therapy may therefore be required. Phenergan may lower the convulsive threshold, and dosage adjustment of anticonvulsant medication may therefore be required. Phenergan may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results. Phenergan 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. Phenergan injection may increase glucose tolerance.

4.6 Fertility, Pregnancy and lactation

Phenergan injection 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

Ambulant patients receiving Phenergan for the first time should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the central nervous effects of the drug and do not suffer from disorientation, confusion or dizziness.

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 (≥1/10,000 to ≥1/1000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Side effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness, and disorientation. Anticholinergic side effects such as blurred vision, dry mouth and urinary retention occur occasionally. Newborn and premature infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability. The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine. Other side-effects include anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, restless legs syndrome, muscle spasms and tic-like movements of the head and face. Jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Very rare cases of allergic reactions, including urticaria, rash, pruritus and anaphylaxis, have been reported. Photosensitive skin reactions have been reported; strong sunlight should be avoided during treatment.

<u>Reporting of suspected adverse reactions</u>

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il

4.9 Overdose

Symptoms of severe overdosage are variable. They are characterized 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. 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

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 slowly excreted via urine and bile. It is distributed widely in the body. It enters the brain and crosses the placenta. Phenothiazines pass into the milk at low concentrations.

5.3 Preclinical safety data

No additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium metabisulfite
Sodium gentisate
Sodium sulfite
Water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date of the product is printed on the package materials.
Once opened/diluted: the product must be used immediately.

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

2 ml in ampoule (colourless glass). Box of 5 ampoules.

6.6 Special precautions for disposal

Discoloured solutions should not be used.

7 MARKETING AUTHORISATION HOLDER

Biomed-JR Ltd.,
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8 MANUFACTURER

Haupt Pharma Livron S.A.S
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9 MARKETING AUTHORISATION NUMBER

167-08-35764-00

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