

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDECINAL PRODUCT

Promethazine Hydrochloride Injection B.P. 2.5% w/v, 1ml & 2ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of solution contains Promethazine Hydrochloride Injection B.P. 2.5% w/v.

3. PHARMACEUTICAL FORM

Colourless or almost colourless sterile solution for injection intended for parenteral administration to human beings.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Promethazine Hydrochloride Injection B.P. 2.5% w/v is indicated

1. in the management of allergic conditions for its anti-histamine properties,
2. as an anaesthetic pre-medication for its sedative, anti-emetic and anti-secretory effects,
3. for sedation and hypnosis.

4.2 Posology and Method of Administration

Method of administration: Deep intramuscular injection. In emergencies, Promethazine Hydrochloride Injection B.P. 2.5% w/v may be administered by slow intravenous injection after dilution (see dosage information).

Adults:

The usual adult dose is 25 to 50mg by deep intramuscular injection. In emergency situation, a 2.5% w/v solution (equivalent to 25mg Promethazine Hydrochloride in 1ml) may be diluted to 10 times its volume with Water for injection and administered by slow intravenous injection at a rate not exceeding 25mg per minute. The maximum parenteral dose is 100mg.

Elderly:

There are no specific dosage recommendation for elderly patients.

Children:

Children aged 5 to 10 years may be given a dose of 6.25 to 12.5mg by deep intramuscular injection.

4.3 Contra-Indication

Promethazine Hydrochloride Injection B.P. should not be used in patients who are in coma or suffering from CNS depression of any cause. It must not be given to patient who are hypersensitive to phenothiazines or to any of the ingredients in the formulation.

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It should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

4.4 Special Warnings and Special Precaution For Use

Because promethazine may thicken or dry lung secretions and impair expectoration, it should be used with caution in patients with asthma, bronchitis or bronchiectasis. It should be used with care in patient 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. Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs such as salicylates. By suppressing vomiting, promethazine may delay the early diagnosis of intestinal obstruction or raised intracranial pressure. Accidental intra-arterial injection may lead to peripheral gangrene and necrosis. Subcutaneous injection may lead to local necrosis. Promethazine hydrochloride should not be used in children under the age of two. Caution should be exercised when administering Promethazine HCl medications to paediatric patients two years of age and older.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

Promethazine may enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Promethazine may interfere with immunologic urine pregnancy tests and produce false positive or false negative results.

Before commencing skin tests using allergen extracts, promethazine should be discontinued for at least 72 hours as it may inhibit the cutaneous histamine response, thus producing false negative results.

Patients, especially if they are elderly, on anti-hypertensive therapy may require adjustment of dosage to avoid postural hypotension.

4.6 Pregnancy and Lactation

Promethazine should not be used in pregnancy unless considered essential by the physician. Use of promethazine in the two weeks prior to delivery is not recommended in view of the risk of irritability and excitement in the neonate.

Although available evidence suggests that the amount excreted in milk is insufficient, there are risks of neonatal irritability and excitement

4.7 Effects on Ability to Drive and Use Machines

Promethazine may impair the mental and/or physical abilities required for driving or operating machinery. Concomitant administration of other central nervous system depressants, including alcohol, may have an additive effect. Patients should be warned accordingly.

4.8 Undesirable Effects

Side effects may be seen in a few patients: drowsiness, dizziness, restlessness, headache, 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 anticholinergic effects and confusion due to promethazine. Other side-effects include anorexia, gastrointestinal disturbance, palpitation, hypotension, arrhythmias, extrapyramidal effects, muscle spasm and tic-like movement of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitivity skin reaction have been reported and strong sunlight should be avoided during treatment. The preservatives in promethazine hydrochloride Injection B.P. have been reported to cause hypersensitivity reactions, characterised by circulatory collapse with CNS depression, in certain susceptible individuals with allergic tendencies.

4.9 Overdose

Symptoms of severe overdosage are variable. Children may display various combination of excitation, ataxia, inco-ordination, athetosis and hallucination, whereas adults may become drowsy and lapse into coma. Convulsion may occur in adults or children and may be preceded by coma or excitement. Cardiorespiratory depression is uncommon. Treatment is symptomatic and supportive and attention should be given to maintaining adequate respiratory and circulatory status. Convulsions may be controlled with diazepam, although its benefits must be weighed against the risk of increased central depressant effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Promethazine is a long-acting antihistamine with additional anti-emetic, anticholinergic and sedative effects. It has phenothiazine derivative.

5.2 Pharmacokinetic Properties

Promethazine Hydrochloride is well absorbed after intramuscular administration. It is widely distributed in the body and it enters the brain and crosses the placenta. The drug is highly plasma protein bound. Promethazine is metabolised in the liver and is slowly excreted via urine and bile.

5.3 Pre-Clinical Safety Data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICALS PARTICULARS

6.1 List of Excipients

Sodium Metabisulphite B.P.
Sodium Sulphite B.P.
Sodium Chloride B.P.
Hydrochloric Acid B.P.
Water for injection B.P.

6.2 Incompatibilities

Solution of promethazine hydrochloride are incompatible with alkaline substances, which precipitate the insoluble promethazine base.

6.3 Shelf Life

Unopened : 3 years (36 months)
After reconstitution : not applicable
After first opening : not applicable*

* If any part of an ampoule is used, discard the remaining solution.

6.4 Special Precaution for Storage

Protect from light.
Store below 25°C.

6.5 Nature and Contents of Container

1ml and 2ml, clear glass ampoules, glass type 1 Ph.Eur. borosilicate glass packed in cardboard cartons to contain 10 x 1ml and 10 x 2ml ampoules.

6.6 Instruction for Use, Handling and Disposal

For deep intramuscular injection.
Use as directed by the physician.
Keep out of reach of children.
If only part used, discard the remaining solution.

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.,
Roscrea,
Co. Tipperary,
Ireland.

8. MARKETING AUTHORISATION NUMBER

PL 2848/0121.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

18/9/1989.

10. DATE OF(PARTIAL) REVISION OF TEXT

September 2007