



SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

**Promethazine Syrup®
(Promethazine Hydrochloride)**

1. NAME OF THE MEDICINAL PRODUCTION

Promethazine syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of the syrup contains promethazine Hydrochloride BP 5

3. PHARMACEUTICAL FORM

Oral 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.
- Prevention and control of nausea and vomiting.
- Active and prophylactic treatment of motion sickness.
- For short term use as a paediatric sedative.

4.2 Posology and method of administration

Age	As an antihistamine in allergy	As an Antiemetic	Short term sedation
Children 2-5 years	5ml-15ml as a single dose. Or 5ml two daily.	5ml to be taken the night before the journey. To be repeated after 6-8 hours as required.	15ml or 20ml as a single night time dose.

Method of administration

For oral administration

Contraindication

Promethazine must not be given to neonates, premature infants or patients hypersensitive to phenothiazines.

Not for use in children under the age of 2 years because the safety of such use has not been established.

Warnings/Precautions

- It should be used with caution in patients with asthma, bronchitis or bronchiectasis.
- It should be used with care in patient with epilepsy or hepatics and renal insufficiency.
- Promethazine should not be used for longer than 7 days without seeking medical advice.
- It should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.3 Drug Interactions

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

4.4 Pregnancy and Lactation

4.5 Effects on ability to drive and use machines

Because the duration of action may be to 12 hours, patient should be advised that if they feel drowsy they should not drive or operate heavy machinery

4.6 Undesirable effects

Side effects may be seen in few patients such as drowsiness, restlessness, headaches, nightmares, tiredness and disorientation.

4.7 Overdose

The patient is seen enough after ingestion, it should be possible to reduce 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 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 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 concentration.

5.3 Preclinical safety data

No additional preclinical data of relevance to the prescriber.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Promethazine Hydrochloride

Sodium Saccharin

Sucrose

Citric Acid

Sodium citrate

Methyl Paraben

Propyl Paraben

Sodium CMC (Medium viscosity)

Sodium Metabisulphite

Sodium sulphite

Caramel Flavour

Banana Flavour

Ethanol 96%

Purified Water (to volume)

Incompatibilities

None stated.

6.2 Shelf life

3 years

6.3 Special precautions for storage

Store below 25°C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container and special equipment for use, administration or implantation

6.6 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

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