

# Promethazine Hydrochloride Tablets USP 12.5mg/25mg/50mg

## 1. Name of the medicinal product

Promethazine Hydrochloride Tablets USP  
12.5mg Taj Pharma  
Promethazine Hydrochloride Tablets USP 25mg  
Taj Pharma  
Promethazine Hydrochloride Tablets USP 50mg  
Taj Pharma

## 2. Qualitative and quantitative composition

a) Each film coated tablet contains:  
Promethazine Hydrochloride USP 12.5mg  
Excipients q.s.  
Colours: Brilliant Blue FCF & Titanium Dioxide  
BP

b) Each film coated tablet contains:  
Promethazine Hydrochloride USP 25mg  
Excipients q.s.  
Colours: Brilliant Blue FCF & Titanium Dioxide  
BP

c) Each film coated tablet contains:  
Promethazine Hydrochloride USP 50mg  
Excipients q.s.  
Colours: Brilliant Blue FCF & Titanium Dioxide  
BP

For full list of excipients, see section 6.1

## 3. Pharmaceutical form

Film coated tablet.

## 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.

As an antiemetic.

For short term use:

Treatment of insomnia in adults.

For short term use as a paediatric sedative.

### 4.2 Posology and method of administration

Route of administration: Oral.

Not for use in children under the age of 2 years (see section 4.3).

#### *As an antihistamine in allergy:*

Children 2-5 years	The use of Promethazine Elixir is recommended for this age group.
Children 5-10 years	25 mg as a single dose*. Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly)	25 mg as a single dose*. Increasing to a maximum of 25 mg bd as required.

\*Single doses are best taken at night.

#### *As an antiemetic:*

Children 2-5 years	The use of Promethazine Elixir is recommended for this age group.
Children 5-10 years	The use of Promethazine Elixir or Promethazine 10 mg Tablets is recommended.
Children over 10 years and adults (including elderly)	25 mg to be taken the night before the journey. To be repeated after 6–8 hours as required.

#### *As a paediatric sedative for short term use and for short term treatment of insomnia in adults:*

Children 2-5 years	The use of Promethazine Elixir is recommended for this age group.
Children 5-10 years	25 mg as a single night time dose.
Children over 10	25 or 50 mg as a single night time dose.

years and adults (including elderly)	
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#### 4.3 Contraindications

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

Promethazine 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..

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

#### 4.4 Special warnings and precautions for use

Promethazine 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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactosemalabsorption should not take this medicine.

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

#### 4.5 Interaction with other medicinal products and other forms of interaction

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

#### 4.6 Fertility, pregnancy and lactation

Promethazine should not be used in pregnancy unless the physician considers it essential. The use of Promethazine 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 CIOMS frequency rating is used: Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1000$  to  $< 1/100$ ); rare ( $\geq 1/10000$  to  $< 1/1000$ ); very rare ( $< 1/10000$ ), 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. 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 urticaria, rash, pruritus, anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

#### 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.

#### **4.9 Overdose**

Symptoms of severe overdose 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. 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.

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 preclinical data of relevance to the prescriber.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Lactose monohydrate, Maize starch, Povidone, Magnesium stearate, Polyethylene glycol, Hypromellose.

Titanium dioxide BP, Brilliant Blue FCF.

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 30°C. Store in the original carton in order to protect from light.

### **6.5 Nature and contents of container**

PVC Aluminium Pack.

Pack Size: 7, 14, 28, 30, 50, 60, 100 and 500 film coated tablets.

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

No special requirements

## **7. Manufactured In India By:**

**TAJ PHARMACEUTICALS LTD.**

Mumbai, India

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Maharashtra chambers of Commerce Lane,  
Fort, Mumbai - 400001  
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