Safety Data Sheet  
Promethazine Hydrochloride Tablets, USP  

**Strength:** 12.5mg/ 25mg/50mg.  
**Pack Size:** 100 Tablets per bottle  
**Revision No.: 02**

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**EMERGENCY OVERVIEW**

Each Promethazine Hydrochloride Tablet, USP intended for oral administration contains Promethazine Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

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**Section 1. Identification**

**Identification of the product**

**Product name:** Promethazine Hydrochloride Tablet, USP  
**Formula:** C17 H20 N2 S .HCl  
**Chemical Name:** 10 H Phenothiazine-10-ethanamine, N, N, α-trimethyl-, monohydrochloride.

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**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd. Ahmedabad, India  
**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319  
**Emergency Telephone No.** Tel.: +91 79 6868100  
**Recommended use / Therapeutic Category** H1 Receptor Blocking Agent  
**Restriction on Use / Contraindications:** Promethazine hydrochloride tablets, USP are contraindicated for use in pediatric patients less than two years of age. Promethazine hydrochloride tablets, USP are contraindicated in Comatose states, and in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines. Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms including asthma.
## Strength: 12.5mg/ 25mg/50mg.  Pack Size: 100 Tablets per bottle  Revision No.: 02

### Section 2. Hazard(s) Information

#### Dose and Administration

**Motion Sickness / Nausea and Vomiting / Sedation**

The average oral dose is 25 mg taken before retiring; however, 12.5 mg may be taken before meals and on retiring.

**Pre- and Postoperative Use**

Promethazine hydrochloride in 12.5- to 25-mg doses for children and 50-mg doses for adults the night before surgery relieves apprehension and produces a quiet sleep.

#### Adverse Effects

**ADVERSE ACTIONS**

**Central Nervous System**

Drowsiness is the most prominent CNS effect of this drug. Sedation, somnolence, blurred vision, dizziness; confusion, disorientation, and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion; lassitude, tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsive seizures, excitation, catatonic-like states, hysteria. Hallucinations have also been reported.

**Cardiovascular**

Increased or decreased blood pressure, tachycardia, bradycardia, faintness.

**Dermatologic**

Dermatitis, photosensitivity, urticaria.

**Hematologic**

Leukopenia, thrombocytopenia, thrombocytopenic purpura, agranulocytosis.

**Gastrointestinal**

Dry mouth, nausea, vomiting, jaundice.

**Respiratory**

Asthma, nasal stuffiness, respiratory depression (potentially fatal) and apnea.

**Other**- Angioneurotic edema. Neuroleptic malignant syndrome

**Paradoxical Reactions**

Hyperexcitability and abnormal movements have been reported.

#### Over Dose Effect

Signs and symptoms of overdose with promethazine hydrochloride range from mild depression of the central nervous system and cardiovascular system to profound hypotension, respiratory depression, unconsciousness, and sudden death.

#### Medical Conditions

Promethazine Hydrochloride Tablets, USP should be used in pediatric patients less than 2 year age because of the potential for fetal respiratory depression.

Postmarketing cases of respiratory depression. Including fatalities, have been reported with use of promethazine Hydrochloride Tablets, USP in pediatric patients less than 2 year of age. Wide range of weight based dosage Promethazine Hydrochloride Tablets, USP have resulted in respiration depression in these patients.

Caution should be exercised when administering Promethazine Hydrochloride Tablets, USP to pediatric patients 2 year of age.
and older. It is recommended that the lowest effective dose of Promethazine Hydrochloride be used in pediatric patients 2 years of the age and older and concomitant administration of other drugs with respiratory depressant effects be avoided.

Contraindications
Promethazine hydrochloride tablets, USP are contraindicated for use in pediatric patients less than two years of age. Promethazine hydrochloride tablets, USP are contraindicated in Comatose states, and in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines. Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms including asthma.

Pregnancy Comments

**Teratogenic Effects- Pregnancy Category C**
Teratogenic effects have not been demonstrated in rat-feeding studies at doses approximately 2.1 to 4.2 times the maximum recommended total daily dose of promethazine for a 50-kg subject.

**Nonteratogenic Effects**
Promethazine hydrochloride tablets, USP administered to a pregnant woman within two weeks of delivery may inhibit platelet aggregation in the newborn.

**Pregnancy Category**

C

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### Section 3. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
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</thead>
<tbody>
<tr>
<td><strong>Principle Component:</strong></td>
<td></td>
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<tr>
<td>Promethazine hydrochloride, 12.5mg, 25mg and 50mg</td>
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<td>58-33-3</td>
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<tr>
<td><strong>Inactive Ingredients:</strong></td>
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<tr>
<td>Hydroxypropyl cellulose,</td>
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<td>Lactose monohydrate,</td>
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<tr>
<td>Low-substitute dhydroxypropyl cellulose</td>
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<td>78214-41-2</td>
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<tr>
<td>Magnesium stearate.</td>
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<td>557-04-0</td>
</tr>
</tbody>
</table>
**Section 4. First-aid measures**

**General**
Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

**Overdose Treatment**
- Treatment of overdosage is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, including respiration, pulse, blood pressure, temperature, and EKG, need to be monitored.
- Activated charcoal orally or by lavage may be given, and Diazepam may be used to control convulsions. Acidosis and electrolyte losses should be corrected.

**Section 5. Fire-fighting measures**

**Flash Point** Not Found  
**Auto-Ignition Temperature:** Not Found  
**Extinguishing Media** Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

**Upper Flammable Limit:** Not Found  
**Lower Flammable Limit:** Not Found  
**Fire and Explosion Hazard** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

**Fire Fighting Procedure** As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

**Section 6. Accidental Release Measures**

**Spill Response** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

**Section 7. Handling and Storage**

**Storage** Store at 20° to 25°C (68° to 77°F). Dispense in a tight, light-resistant container. Protect from light.

**Incompatibilities:** Reactive with oxidizing agents.
Section 8. Exposure controls / personal protection

Respiratory Protection  Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection  Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection  Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing  Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control  Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and chemical properties

Appearance  • Promethazine Hydrochloride Tablets, USP, 12.5 mg are white to off white, round shape, biconvex, uncoated tablets debossed with the logo of “ZC”, “01” and bisect on one side and plain on the other side.

• Promethazine Hydrochloride Tablets, USP, 25 mg are white to off white, round shape, biconvex, uncoated tablets debossed with the quadrisection and the logo of “Z”, “C”, “0” and “2” on one side and plain on the other side.

• Promethazine Hydrochloride Tablets, USP, 50 mg are white to off white, round shape, biconvex, uncoated tablets debossed with the logo of “ZC03” on one side and plain on the other side.

Solubility in water  No Data Available  Odour  Odourless

Boiling point  No Data Available  Melting Point  No Data Available

Evaporation rate  No Data Available  Vapour density  No Data Available

Reactivity in water  No Data Available  Evaporation rate  No Data Available

% Volatile by volume  No Data Available  Specific gravity  No Data Available

Vapour pressure  No Data Available

Other information  Promethazine hydrochloride is a racemic compound; the molecular formula is C17H20N2S.HCl and its molecular weight is 320.88. It occurs as a white to faint yellow, practically odorless, crystalline powder which slowly oxidizes and turns blue on prolonged exposure to air. It is freely soluble in water, in hot dehydrated
Section 10. Stability and Reactivity

**Condition to avoid**
Avoid exposure to extreme heat, light and moisture.

**Stable**
Stable under normal ambient and anticipated storage and handling conditions.

**Decomposition Products**
No Data Available

**Hazardous Reaction**
No data available.

**Incompatibilities:**
Reactive with oxidizing agents.

Section 11. Toxicological information

**General**
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

**Target organ**
Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

**Other**
No Data available

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 040596
Section 16. Other information

None

Date of issue: 28/05/2015

The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.