EMERGENCY OVERVIEW

PROMETHAZINE HYDROCHLORIDE TABLET contain Promethazine and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name: Promethazine Hydrochloride Tablets
Formula: C_{17}H_{20}N_{2}S.HCl
Chemical Name: 10 H Phenothiazine-10-ethanamine, N, N, α-trimethyl-, monohydrochloride.
Therapeutic Category: H1 Receptor Blocking Agent

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

Section 2. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle Component</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promethazine Hydrochloride, 12.5mg, 25 mg and 50 mg</td>
<td>Not Found</td>
<td>58-33-3</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl cellulose,</td>
<td>Not Found</td>
<td>9004-64-2</td>
</tr>
<tr>
<td>Lactose monohydrate,</td>
<td>Not Found</td>
<td>64044-51-5</td>
</tr>
<tr>
<td>Low-substituted hydroxypropyl cellulose</td>
<td>Not Found</td>
<td>78214-41-2</td>
</tr>
<tr>
<td>Magnesium stearate.</td>
<td>Not Found</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>
Section 3. Health Hazards Information

Dose and Administration

DOSAGE 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 REACTIONS
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

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

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
**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 | Upper Flammable Limit: | Not Found |
| Auto-Ignition Temperature: | Not Found | Lower Flammable Limit: | Not Found |
| Extinguishing Media | Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material. | 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. Storage / Spill / Disposal Measures**

**Storage**

**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.

**Disposal**
Dispose the waste in accordance with all applicable Federal, State and local laws.
Section 7. Exposure controls and 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.

Section 8. 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 quadrisept 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

Percentage 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 alcohol, and in chloroform; practically insoluble in ether, in acetone and in ethyl acetate.
Material Safety data sheet
Promethazine Hydrochloride Tablets, USP

Strength: 12.5 mg / 25 mg./50mg.  Pack Size: 100 Tablets per bottle  Revision No.: 00

### Section 9. Physical Hazards

<table>
<thead>
<tr>
<th>Condition to avoid</th>
<th>Decomposition Products</th>
<th>Stable</th>
<th>Hazardous Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid exposure to extreme heat, light and moisture.</td>
<td>No Data Available</td>
<td>Stable under normal ambient and anticipated storage and handling conditions.</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

Incompatibilities: No data available.

### Section 10. 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.

### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Other information

None

Date of issue: 29/08/05  Supersedes edition of: New Edition

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.