Material Safety data sheet

Promethazine Hydrochloride Tablets, USP

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

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:	$C_{17}H_{20}N_2S.HCl$
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

Component	Exposure Limit	CAS No.
Principle Component :		
Promethazine Hydrochloridel, 12.5mg, 25 mg and 50 mg	Not Found	58-33-3
Inactive Ingredients :		
Hydroxypropyl cellulose,	Not Found	9004-64-2
Lactose monohydrate,	Not Found	64044-51-5
Low-substituted hydroxypropyl cellulose	Not Found	78214-41-2
Magnesium stearate.	Not Found	557-04-0

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 contiminated Clothing. Person devloping 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	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container. Protect from light
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 quadrisect 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.

Section 9. Physical Hazards

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	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.
other	

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.