Safety Data Sheet
Promethazine Hydrochloride Tablets, USP

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

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.

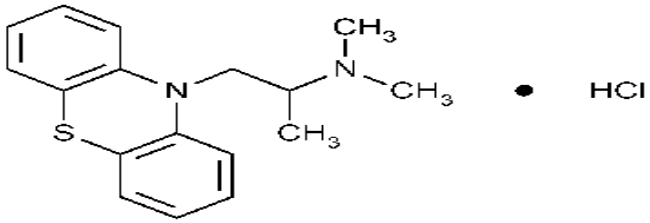
Section 1. Identification

Identification of the product

Product name: **Promethazine Hydrochloride Tablet, USP**

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

Chemical Name: 10 H Phenothiazine-10-ethanamine, N, N, α-trimethyl-, monohydrochloride.



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

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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.

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 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.

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 2years 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**

Section 3. Composition / information on ingredients

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

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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. 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 quadrisect and the logo of “Z”, “C”, “0” and “2” on one side and plain on the other side.
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- 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

alcohol, and in chloroform; practically insoluble in ether, in acetone and in ethyl acetate.

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 **Supersedes edition of:** 01

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.