Safety Data Sheet **Revision No.:** 00

Diltiazem Hydrochloride Tablets, USP, Strength: 30mg, 60mg, 90mg and 120mg

Pack Size: 100 and 500 Tablets per bottle

EMERGENCY OVERVIEW

Each Diltiazem Hydrochloride Tablets USP intended for oral administration contains Diltiazem Hydrochloride and excipients generally considered non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

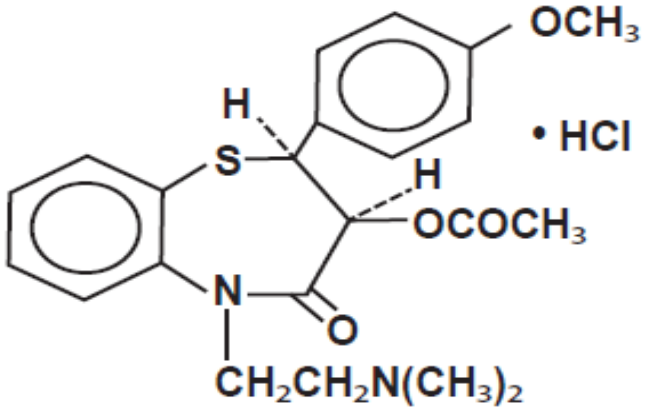
Section 1. IDENTIFICATION

Identification of the product

Product Name: Diltiazem Hydrochloride Tablets USP

Formula: $C_{22}H_{26}N_2O_4S.HCl$

Chemical Name:



Manufacturer / Supplier identification

Company:	**Zydus Lifesciences Limited**
Address:	**Zydus Lifesciences Limited**, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.
Contact for information:	Tel: +91-1795-246841
Emergency Telephone No.	Tel: +91-1795-252300

Recommended use / Therapeutic Category

INDICATIONS AND USAGE Diltiazem hydrochloride tablets are indicated for the management of chronic stable angina and angina due to coronary artery spasm.

Restriction on Use/
Contraindications: **Diltiazem hydrochloride tablets are contraindicated in:**

- Patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker.
- Patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker.
- Patients with hypotension (less than 90 mm Hg systolic).
- Patients who have demonstrated hypersensitivity to the drug.
- Patients with acute myocardial infarction and pulmonary congestion documented by x-ray on admission.

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration

For Oral Administration Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at 1- to 2-day intervals until optimum response is obtained.

Adverse Effects Edema, headache, nausea, dizziness, rash, and asthenia

Cardiovascular: Angina, arrhythmia, AV block (first-degree), AV block (second- or third-degree, bradycardia, bundle branch block, congestive heart failure, ECG abnormality, flushing, hypotension, palpitations, syncope, tachycardia, ventricular extrasystoles

Nervous System: Abnormal dreams, amnesia, depression, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tremor

Gastrointestinal: Anorexia, constipation, diarrhea, dysgeusia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH, thirst, vomiting, weight increase.

Dermatological: Petechiae, photosensitivity, pruritus, urticaria

Other: Amblyopia, CPK elevation, dry mouth, dyspnea, epistaxis, eye irritation, hyperglycemia, hyperuricemia, impotence, muscle cramps, nasal congestion, nocturia, osteoarticular pain, polyuria, Sexual

	difficulties, Tinnitus.
Over Dose Effect	Diltiazem overdose included bradycardia, hypotension, heart block, and cardiac failure.
Pregnancy Comments	There are no well-controlled studies in pregnant women; therefore, use diltiazem hydrochloride in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Diltiazem Hydrochloride	Not Found	33286-22-5
Inactive Ingredients:		
Lactose Monohydrate	Not Found	10039-26-6
Microcrystalline Cellulose	Not Found	9004-34-6
Hypromellose	Not Found	9004-65-3
Colloidal Silicon Dioxide	Not Found	7631-86-9
Magnesium Stearate	Not Found	557-04-0
Opadry Green 03B510098 (30mg and 90mg)	Not Found	Not found
Opadry White 03B580040 (60 mg and 120mg)	Not Found	Not Found

Section 4. FIRST-AID MEASURES

Inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
Skin Contact	Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
Eye Contact	Hold eyelids apart and flush eyes with plenty of water. Have eyes examined and tested by medical personnel.
Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by

	medical personnel. Get immediate medical attention.

Section 5. FIRST FIGHTING MEASURES

Extinguishing Media	Use carbon dioxide, dry chemical or water spray.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. Fire
Explosion Hazards:	Not applicable

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7. HANDLING AND STORAGE

Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Avoid excessive humidity.
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. However, no personal respiratory protective equipment normally required.

Skin Protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/Face Protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary; however, it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Color	30 mg and 90mg: Green colored 60mg and 120mg: White to off white colored
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Stable under normal conditions of use
Incompatibility materials to avoid	Keep away from Strong Oxidizing agents
Polymerization	Will not occur

Section 11. TOXILOGICAL INFORMATION

Skin contact	No irritating effect.
Eye contact	No irritating effect.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Section 12. ECOLOGICAL INFORMATION

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

Section 13. DISPOSAL CONSIDERATION

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

Section 14. TRANSPORT INFORMATION

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

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number: 219253

Section 16. OTHER INFORMATION

Date of issue: February 12, 2025 **Supersedes edition:** 00

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.