

## DILZEM CD

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only**

Abbreviated Prescribing information for DILZEM CD [Diltiazem Hydrochloride Extended-Release Capsules U.S.P]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** Diltiazem produces its antihypertensive effect by relaxing vascular smooth muscle, decreasing peripheral vascular resistance, with the blood pressure reduction varying based on the degree of hypertension. Diltiazem increases exercise tolerance by reducing myocardial oxygen demand, dilates coronary arteries, inhibits coronary spasms, and increases coronary blood flow with minimal negative inotropic effects, while lowering blood pressure and peripheral resistance.

**INDICATIONS:** Dilzem CD is indicated in the management of angina pectoris particularly chronic stable angina. It can be used concomitantly with beta blockers and/or nitrates in patients of angina who remain symptomatic despite adequate doses of the latter. It may also be used in angina due to coronary artery spasm. Dilzem CD is also indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications.

**DOSAGE AND ADMINISTRATION: Hypertension:** Adjust dosage to individual patient needs. When used as monotherapy reasonable starting doses are 180 to 240 mg once daily, although some patients may respond to lower doses. Maximum antihypertensive effect is usually observed by 14 days of chronic therapy; therefore, schedule dosage adjustments accordingly. The usual dosage range studied in clinical trials was 240 to 360 mg once daily. Individual patients may respond to higher doses of up to 480 mg once daily. **Angina:** Dosages for the treatment of angina should be adjusted to each patient's needs, starting with a dose of 120 or 180 mg once daily. Individual patients may respond to higher doses of up to 480 mg once daily. When necessary, titration may be carried out over a 7- to 14-day period.

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

**WARNINGS AND PRECAUTIONS:** Diltiazem may cause cardiac conduction issues, including slow heart rates or AV block, particularly in patients with sick sinus syndrome, and can worsen heart failure in those with impaired ventricular function. It may lead to symptomatic hypotension, mild liver enzyme elevations, and rare acute hepatic injury, while requiring monitoring of liver and kidney function; dermatologic reactions, including serious skin eruptions, may also occur.

**DRUG INTERACTION:** Diltiazem hydrochloride can interact with several medications, affecting their efficacy and side effect profiles, particularly with agents that influence cardiac contractility, conduction, or CYP3A4 metabolism. Co-administration with drugs like beta-blockers, statins, or benzodiazepines may require dose adjustments due to additive effects or altered pharmacokinetics, such as increased plasma levels

**ADVERSE REACTIONS:** Headache, dizziness, bradycardia, AV block first degree, edema, asthenia, congestive heart failure, palpitations, syncope, ventricular extrasystoles, insomnia, nervousness, paresthesia, personality change, somnolence, tinnitus, tremor, anorexia, constipation, diarrhea, dry mouth, dysgeusia, dyspepsia, mild elevations of SGOT, SGPT, LDH and alkaline phosphatase, thirst, vomiting, weight increase, petechiae, photosensitivity, pruritus, urticaria, Amblyopia, CPK increase, dyspnea, epistaxis, eye irritation, hyperglycemia, hyperuricemia, impotence, muscle cramps, nasal congestion, nocturia, osteoarticular pain, polyuria, sexual difficulties.

### MARKETED BY



TORRENT PHARMACEUTICALS LTD.

**IN/DILZEM CD 90,120,180mg/DEC-19/03/ABPI**