

DILZEM CD

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

Abbreviated Prescribing information for DILZEM CD (Diltiazem Hydrochloride 120 mg and 180 mg Extended Release Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Diltiazem hydrochloride is a calcium ion cellular influx inhibitor (slow channel blocker or calcium antagonist). It produces its antihypertensive effect primarily by relaxation of vascular smooth muscle and the resultant decrease in peripheral vascular resistance.

INDICATIONS: For the management of angina pectoris and for treatment of hypertension.

DOSAGE AND ADMINISTRATION: Hypertension: Dosage needs to be adjusted by titration to individual patient needs. When used as mono- therapy starting doses are 120-240 mg once daily. Individual patient may respond to higher doses up to 480mg once daily. **Angina:** Dosages should be adjusted to each patient's needs, starting with a dose of 120 once daily. Individual patient may respond to higher doses of up to 480mg once daily.

CONTRAINDICATION: Contraindicated in women of child bearing potential or lactating mothers, patients with severe bradycardia, second or third degree heart block, in patients without a functioning pacemaker or sick sinus syndrome, patients with impaired renal function, hepatic dysfunction, cardiac failure after myocardial infarction, left ventricular failure with pulmonary stasis, concomitant administration of dantrolene infusion, hypersensitivity to diltiazem or to any of the excipients and concomitant use of alcohol.

WARNINGS & PRECAUTIONS: Cautions should be taken in patients with reduced left ventricular function, mild bradycardia, first degree AV block or prolonged PR interval, in patients with acute porphyria, prior to general anaesthesia, the elderly and in patients with renal or hepatic insufficiency, mood changes including depression, in patients at risk to develop an intestinal obstruction and patients should not drive or operate machinery if affected.

DRUG INTERACTIONS: Anti-hypertensives or other hypotensive agents, dantrolene, alcohol, alpha antagonists, beta blockers, amiodarone, digoxin, antiarrhythmic agents, nitrate derivatives, ciclosporin, carbamazepine and theophylline, lithium, anti-h₂ agents (cimetidine and ranitidine), rifampicin, statins, benzodiazepines and corticosteroids (methylprednisilone)

ADVERSE REACTIONS: Nervousness, insomnia, headache, dizziness, tremors, paraesthesia, atrioventricular block, bradycardia, sinoatrial block, palpitations, ankle oedema, flushing, orthostatic hypotension, constipation, dyspepsia, gastric pain, nausea, vomiting, diarrhoea, dry mouth, hepatic enzymes increase, hepatitis, erythema, urticaria, erythema, lower limb oedema, malaise, fatigue, thrombocytopenia, mood changes (including depression), extrapyramidal syndrome, congestive heart failure, vasculitis, gingival hyperplasia, hepatitis, elevation of liver transaminase, photosensitivity, angioneurotic oedema, erythema multiforme (including steven-johnson's syndrome and toxic epidermal necrolysis), sweating, exfoliative dermatitis, acute generalized exanthematous pustulosis, occasionally desquamative erythema with or without fever and gynaecomastia.

MARKETED BY:



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(Additional information is available on request)