DILZEM

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

Abbreviated Prescribing information for DILZEM (Diltiazem Hydrochloride 30 mg, 60 mg Tablets) [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 mild to moderate hypertension

DOSAGE AND ADMINISTRATION: As per the physician direction.

CONTRAINDICATION: 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, patients with hypersensitivity to the drug and patients with acute myocardial infarction and pulmonary congestion.

WARNINGS & PRECAUTIONS: Cardiac Conduction: Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. Congestive Heart Failure: Experience with the use of diltiazem in combination with beta-blockers in patients with impaired ventricular function is limited. Hypotension: Decreases in blood pressure associated with diltiazem therapy may occasionally result in symptomatic hypotension. Acute Hepatic Injury: In rare instances, significant elevations in enzymes such as alkaline phosphatase, LDH, SGOT, SGPT, and other phenomena consistent with acute hepatic injury have been noted. Skin eruptions progressing to erythema multiforme and/or exfoliative dermatitis have also been reported. If dermatologic reaction persist, the drug should be discontinued.

DRUG INTERACTIONS: Co-administration with a stronger CYP3A4 inhibitor (e.g. cilostazol, ivabradine, sirolimus, tacrolimus), lithium, nitrate derivatives, theophylline, alpha-antagonists, amiodarone, digoxin, beta-blockers, other antihypertensive drugs, other antiarrhythmic agents, carbamazepine, rifampicin, barbiturates (phenobarbital, primidone), phenytoin, anti-H₂ agents (cimetidine, ranitidine), protease inhibitors (atazanavir, ritonavir), ciclosporin, barbiturates (phenobarbital, primidone) and phenytoin, benzodiazepines (midazolam, triazolam), corticosteroids (methylprednisolone) and statins (simvastatin, atorvastatin, lovastatin).

ADVERSE REACTIONS: Thrombocytopenia, nervousness, insomnia, mood changes, headache, dizziness, extrapyramidal syndrome, atrioventricular block, bradycardia, sinoatrial block, congestive heart failure, flushing, orthostatic hypotension, vasculitis, constipation, dyspepsia, gastric pain, nausea, vomiting, diarrhea, dry mouth, gingival hyperplasia, gastrointestinal disorder, hepatic enzymes increase, hepatitis, erythema, urticaria, photosensitivity, angioneurotic oedema, rash, erythema multiforme, hyperhidrosis, exfoliative dermatitis, acute generalized exanthematous pustulosis, occasionally desquamative erythema with or without fever, allergic dermatitis, gynecomastia, peripheral oedema, malaise, fatigue.



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IN/DILZEM 30 and 60mg/Jul-2015/01/AbPI (Additional information is available on request)