DILZEM SR

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

Abbreviated Prescribing information for DILZEM SR (Diltiazem Hydrochloride 90mg sustain release 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 for treatment of mild to moderate hypertension.

DOSAGE AND ADMINISTRATION: Hypertension: Dosage needs to be adjusted by titration to individual patient needs. When used as mono- therapy starting doses are 180-240 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, sta rting with a dose of 120 or 180 mg once daily. Individual patient may respond to higher doses of up to 480mg once daily.

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 persists, the drug should be discontinued.

DRUG INTERACTIONS: Anesthetics, benzodiazepines, beta-blockers, buspirone, carbamazepine, cimetidine, clonidine, cyclosporine, digitalis, quinidine, rifampin and statins.

ADVERSE REACTIONS: Acute generalized exanthematous pustulosis, allergic reactions, alopecia, angioedema (including facial or periorbital edema), asystole, erythema multiforme (including Stevens- Johnson syndrome, toxic epidermal necrolysis), exfoliative dermatitis, extrapyramidal symptoms, gingival hyperplasia, hemolytic anemia, increased bleeding time, leukopenia, photosensitivity (including lichenoid keratosis and hyperpigmentation at sun-exposed skin areas), purpura, retinopathy, myopathy, and thrombocytopenia, myocardial infarction, generalized rash and lukocytoclastic vasculitis.

MARKETED BY:

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(Additional information is available on request)