DILZEM SR

(Sustained Release Diltiazem Hydrochloride Tablets, 90 mg)

COMPOSITION

Each sustained release uncoated tablet contains:
Diltiazem Hydrochloride U.S.P. 90 mg

DESCRIPTION

DILZEM SR is a sustained preparation of Diltiazem, a calcium antagonist acting on cardiovascular system. The sustained release preparation of Diltiazem is so formulated that it maintains effective plasma levels when given twice daily at an interval of 12 hours. It is indicated in the management of angina pectoris particularly chronic stable angina. It has also been used extensively in hypertension in America

CLINICAL PHARMACOLOGY

The beneficial effects of Diltiazem in a patient of angina and hypertension are due to its property to inhibit the influx of calcium ion during membrane depolarization. Diltiazem dilates the coronary blood vessels and thereby increases oxygen supply of the myocardium. The decrease in afterload due to peripheral vasodilatation caused by Diltiazem also results in decrease in oxygen requirement of the myocardium.

Diltiazem is well absorbed from the gastrointestinal tract in a constant proportion and undergoes an extensive first pass metabolism resulting in an absolute bioavailability of about 40% which is dose dependent. Peak plasma concentrations are obtained within 3 to 4 hours of oral administration. The apparent elimination half-life after single or multiple dose is 5 to 7 hours. Diltiazem is almost completely metabolized in the liver and only 2 to 4% of the unchanged drug appears in the urine.

INDICATIONS

DILZEM SR 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. **DILZEM SR** has also been extensively used in America in management of mild and moderate hypertension either alone or in combination with diuretics, beta-blockers or angiotensin converting enzyme inhibitors.

CONTRAINDICATIONS

DILZEM SR is contraindicated in patients with sick sinus syndrome, patients with second or third degree AV block and patients with acute myocardial infarction and pulmonary congestion.

PRECAUTIONS

DILZEM SR should be used with caution in patients with impaired hepatic function.

Use in pregnancy, lactation and children

There are no well-controlled studies in pregnant women and Diltiazem should be used only if the optimal benefits of therapy outweighs the potential risk to the fetus. Diltiazem is excreted in human milk, so if use of Diltiazem is essential in nursing mothers an alternative method of infant feeding should be employed. Safety in children has not been established.

ADVERSE REACTIONS

Compared to other calcium antagonists, Diltiazem causes minimum adverse reactions. The most common mild adverse reactions constitute edema, headache, dizziness, asthenia, bradycardia, nausea and rash.

DRUG INTERACTIONS

Use of beta-blockers or digitalis along with Diltiazem may produce additive effects in prolonging AV conduction. However, clinical studies suggest that such a use is well tolerated. Nifedipine given concomitantly with Diltiazem may produce synergistic effect and may be beneficial in certain circumstances.

DOSAGE AND ADMINISTRATION

The recommended dose of **DILZEM SR** is one tablet twice a day. If necessary, 3 tablets per day or 2 tablets twice a day may also be used to suit the requirement of the patient of angina.

STORAGE

Store below 30^{o}C, Protected from light & moisture.

PRESENTATION

DILZEM SR is available in blister strip of 10 tablets and in bottle pack also; each tablet containing 90 mg Diltiazem Hydrochloride U.S.P. in sustained release form.

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Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Baddi 173 205, Dist. Solan (H.P.) INDIA.