DILZEM

(Diltiazem Hydrochloride Tablets U.S.P., 30mg & 60mg)

Dilzem (Diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Each tablet of Dilzem contains either 30mg or 60mg of Diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY:

The pharmacological effects of Dilzem are believed to be related to its ability to inhibit the influx of calcium ion during membrane depolarization of cardiac and vascular smooth muscles.

In men, Dilzem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure. In exercise tolerance tests in patients with ischemic heart disease, Dilzem reduces the heart rate - blood pressure product for any given work load. In studies carried out in patients with good ventricular function, Dilzem has not revealed evidence of a negative inotropic effect on cardiac output, ejection fraction and left ventricular end-diastolic pressure. Resting heart rate is usually unchanged or slightly reduced by Dilzem.

Pharmacokinetics:

Dilzem is absorbed from a tablet formulation to about 80% and is subject to an extensive first-pass effect, giving an absolute bioavailability of about 40%. Dilzem undergoes extensive hepatic metabolism and only 2 to 4% of the unchanged drug appears in the urine. Dilzem is found to bind with plasma proteins to an extent of 70 to 80%. Single oral doses of 30 to 120mg of Dilzem result in detectable plasma levels within 30 minutes and peak plasma levels 2 to 3 hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10 to 20% of the parent compound and is 25 to 50% as potent a coronary vasodilator as Dilzem. Therapeutic blood levels of Dilzem appear to be in the range of 50 to 100mg/ml. There is a departure from dose- linearity when single doses above 60mg are given and a dose of 120mg gave blood levels three times that of the 60mg dose.

INDICATIONS:

1. Dilzem is indicated in the treatment of angina pectoris due to coronary artery spasm. It is particularly effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occuring during attacks).
2. Dilzem is also indicated in the management of chronic stable angina in patients who cannot tolerate therapy with beta blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

CONTRAINDICATIONS:

1. Patients with sick sinus syndrome.
2. Patients with second or third degree AV block.
3. Patients with hypotension (less than 90mm Hg systolic).

DRUG INTERACTIONS:

Use of β-blockers or digitalis concomitantly with Dilzem may produce additive effects in prolonging AV conduction. However, clinical studies suggest that concomitant use of Dilzem and β-blockers or digitalis in usually well tolerated.

USE IN PREGNANCY & LACTATION :

There are no well-controlled studies in pregnant women; therefore, the use of Dilzem in pregnant women should be done only if the optimal benefit justifies the potential risk to the foetus.

It is not known whether Dilzem is excreted in human milk and hence, it should be used in nursing mothers only if benefits are thought to outweigh its potential risk in this situation.

USE IN CHILDREN:

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Serious adverse reactions have been rare and are not more than those reported during placebo therapy. In addition, the following reactions have been found to be of common occurrence : nausea (2.7%), swelling/edema (2.4%), arrhythmia (2%), headache (2%), rash(1.8%), and fatigue (1.1%).

OVERDOSAGE OR EXAGGERATED RESPONSE:

Single oral doses of 300mg of Dilzem have been tolerated by healthy volunteers. In the event of over dosage or exaggerated response, gastric lavage may be given and patient may be treated symptomatically.

DOSAGE AND ADMINISTRATION:

Dosage must be adjusted to each patient's needs. Starting with 30mg four times orally daily, before meals and at bedtime, dosage should be increased gradually to 240mg (given in divided doses three to four times daily) at one to two day intervals until optimum response is obtained. In patients with impaired renal or hepatic function, the dose of Dilzem should be carefully titrated.

PRESENTATION:

Dilzem is available as 30mg and 60mg tablets in blister strip of 10 tablets.

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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