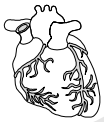

Diltizem® SR 90

Diltiazem

Calcium Antagonist

COMPOSITION

Diltizem® SR 90 tablet : Each tablet contains Diltiazem hydrochloride USP 90 mg as sustained release preparation.

PHARMACOLOGY

Diltizem® (Diltiazem hydrochloride) is a calcium channel antagonist. It is a peripheral and coronary vasodilator with some negative inotropic activity. Diltiazem inhibits cardiac conduction particularly at the sino-atrial and atrioventricular nodes. Diltizem® has the following actions:

*Antianginal***:** A direct dilatation of coronary arteries and arterioles proved oxygen supply to myocardial tissues. In addition dilatation of the peripheral vasculature reduces systemic pressure of cardiac "after load" which results in lessened stress and reduced oxygen requirements of the myocardial tissues.

*Antiarrhythmic***:** The inhibited influx of calcium ions in cardiac tissues result in slowed electrophysiological activity through the S-A and A-V nodes without affecting accessory bypass conduction or altering normal atrial action potential or intraventricular conduction.

*Antihypertensive***:** Reduces peripheral vascular resistance as a result of vasodilatation.

More than 90% of an oral dose is rapidly absorbed. Protein binding is very high. Peak plasma concentration reaches within 30-60 minutes. It is metabolised in the liver and excreted (60%) through bile.

INDICATION

Diltizem® is indicated in the prophylaxis and treatment of angina pectoris. It is used in the management of classical and vasospastic angina pectoris. It has also been used in the treatment of essential hypertension. It is used for prophylaxis of some selected supraventricular tachyarrhythmias.

DOSAGE AND ADMINISTRATION

*Mild to moderate hypertension***:** initially 90 mg or 120 mg twice daily (elderly once daily); up to 360 mg daily may be required (elderly upto 240 mg) daily.

*Angina***:** initially 90 mg or 120 mg twice daily in divided doses may be required (elderly up to 240 mg daily).

Diltizem® SR 90

CONTRAINDICATION AND PRECAUTION

Diltizem® SR is contraindicated in patients with known hypersensitivity to the drug, sick sinus syndrome, second or third degree AV block, severe hypertension or acute myocardial infarction and rediographically documented pulmonary congestion.

SIDE EFFECT

Bradycardia, sino-atrial block, atrioventricular block, hypertension, malaise, headache, hot flushes, GIT disturbances, oedema, hepatitis and depression reported.

DRUG INTERACTION

Concomitant prophylactic therapy with short-or long-acting nitrates may be administered safely during diltiazem therapy. Diltiazem recommended caution and careful dosage titration when diltiazem is administered concomitantly with other drugs that can affect cardiac contractility and/ or conduction.

USE IN PREGNANCY AND LACTATION

There are no adequate and controlled studies to date with diltiazem in pregnant women, and the drug should be used during pregnancy only when the potential benefits justify the possible risk to the fetus.

Because diltiazem is distributed into milk, women receiving the drug should not breastfeed their infants; an alternative method of infant feeding should be used if diltiazem therapy is considered necessary in nursing women.

STORAGE CONDITION

Keep medicine out of the reach of children. Store in a cool and dry place.

HOW SUPPLIED

Diltizem® SR 90 tablet : Box containing 4 x 10 tablets in blister pack.