Diltizem

Diltizem tablet 30-60 mg, 48 tablets
Diltizem SR tablet 90-120 mg, 48 tablets
Diltizem SR tablet 240 mg, 16-32 tablets

COMPOSITION: Each tablet contains 30-60-90-120-240 mg diltiazem HCl.

PHARMACOLOGICAL PROPERTIES:
- A calcium channel blocker
- Blocks slow-channel receptors and prevents calcium ion entry into cells
- Provides vasodilatation in cardiac muscle and vascular smooth muscles
- Decreases afterload
- Decreases preload
- Increases coronary blood flow
- Decreases heart rate
- Increases renal blood flow and provides diuresis
- Low side effect profile
- Well tolerated by patients


CONTRAINDICATIONS: It should not be used in patients hypersensitive to diltiazem; patients with sick-sinus syndrome or II./III. degree AV block in whom no ventricular pace-maker is used; hypotensive patients with systolic blood pressure < 90 mmHg; patients with acute myocardial infarction; and patients with radiologically proven lung congestion.

WARNINGS AND PRECAUTIONS: Diltiazem prolongs AV node refractory period without significantly prolonging sinus node recovery time except in patients with sick sinus syndrome. This effect may rarely result in the slowing of heart rate or II. or III. degree AV block. Concomitant use of diltiazem with β-blockers or digitalis preparations may result in additive effects on cardiac conduction. Therefore, it should be administered with caution, especially in patients with cardiac failure. Possibility of development of hypotension during therapy should be considered. Since diltiazem is metabolized in the liver and excreted in bile and urine, it should be used with caution in patients with hepatic and renal failure and the patients should be closely monitored. Safety of administration of diltiazem in pregnant or nursing women has not been determined. This risk factor should always be considered according to the indication. Safety of administration of diltiazem in children has not been determined.

SIDE EFFECTS / ADVERSE EFFECTS: Nausea, edema, arrhythmia and headache are the most commonly observed side effects (2-3 %). Other side effects observed rather infrequently are: Cardiovascular system: Flushing, palpitation, bradycardia, hypotension, syncope, cardiac failure. Central nervous system: Dizziness, somnolence, nervousness, depression, fatigue, insomnia, confusion, hallucinations. Gastrointestinal system: Dyspepsia, vomiting, diarrhea or constipation, pyrosis. Dermatologic: Urticaria, pruritus. Other: Photosensitivity, polyuria, nocturia, paresthesia and osteoarticular pains. Increases in SGOT, SGPT, LDH, and CPK are slight and transient.
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**DRUG INTERACTIONS:** Coadministration of diltiazem with β-blockers or digitalis preparations can augment its effect on cardiac conduction. When used concomitantly with cimetidine, since first-pass metabolism is inhibited, serum diltiazem concentrations can be elevated. When used concomitantly with carbamazepine, it can inhibit the carbamazepine metabolism and this increases the risk for neurotoxicity. When cyclosporine A is given concomitantly with diltiazem, cyclosporine A plasma levels can be elevated. Coadministration of lithium and calcium channel blockers can cause neurotoxicity. Calcium channel blockers, when used concomitantly, can interact with nitrates. Concomitant use of calcium channel blockers with analgesic agents can produce an increase in hypotensive effect. Coadministration with other calcium channel blockers can cause an additive effect.

**Dosage and Administration:**

**Hypertension therapy:** The recommended daily dosage of Diltiazem tablet in the treatment of hypertension varies between 120-180-240 and 360 mg. Angina pectoris therapy: Treatment of angina pectoris can be started with 30 mg Diltizem tid. When necessary, this dosage can be increased gradually. Since Diltiazem SR 90-120 mg tablets provide continuous release for 12 hours, a twice-daily dosage schedule (mornings and at bed-time) is recommended. Since Diltiazem SR 240 tablets provide continuous release for 24 hours, the drug should be taken in the mornings. The maximum total daily dose is 360 mg. The tablets should be swallowed on an empty stomach without breaking or chewing them.

**Overdosage:** In case of diltiazem overdosage, gastric lavage and supportive measures should be employed, where required. If bradycardia develops, atropine (0.60 mg-1 mg) should be given, and if there is no response, isoproterenol should be given with caution. AV block can be treated in the same manner; in case of permanent block, cardiac pace-maker should be used. If cardiac failure develops during therapy, inotropic agents (isoproterenol, dopamine, dobutamine) and diuretics should be administered. Hypotension can be treated with vasopressor agents (dopamine, levartenol bi-tartarate).

**Storage Conditions:** Should be kept out of reach of children, at room temperature (< 25ºC), away from light and in its package.

**Available Forms:**
- DILTIZEM tablet 30-60 mg, 48-tablets blister packs.
- DILTIZEM SR tablet 90-120 mg, 48 tablets blister packs.
- DILTIZEM SR tablet 240 mg, 16-32 tablets blister packs.

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