

Important: Read Carefully!

AmvascTM

amlodipine besylate

Capsule

COMPOSITION:

Each AmvascTM 2.5 mg capsule contains 2.5 mg amlodipine as base.

Each AmvascTM 5 mg capsule contains 5 mg amlodipine as base.

Each AmvascTM 10mg capsule contains 10mg amlodipine as base.

ACTION & CLINICAL PHARMACOLOGY:

AmvascTM is a calcium ion influx inhibitor (calcium entry blocker or calcium ion antagonist). Amlodipine is a member of the dihydropyridine class of calcium antagonists.

Mechanism of Action:

AmvascTM inhibits transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells.

The antihypertensive mechanism by which amlodipine reduces arterial blood pressure involves direct peripheral arterial vasodilation and reduction in peripheral vascular resistance.

The precise mechanism by which amlodipine relieves angina has not been fully delineated but amlodipine reduces the total ischemic burden by the following two actions:

- Amlodipine dilates the peripheral arterioles and thus reduces the total peripheral resistance (afterload) against which the heart works. The unloading of the heart is thought to decrease ischemia and relieve effort angina by reducing myocardial energy oxygen consumption and oxygen requirements.

- The mechanism of action of amlodipine probably involves dilation of the main coronary arteries and coronary arterioles both in normal and ischemic regions. This dilation increases myocardial oxygen delivery in patients with coronary artery spasm and could oppose the coronary vasoconstriction induced by smoking.

INDICATIONS:

HYPERTENSION

AmvascTM is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients.

AmvascTM should normally be used in those patients in whom treatment with diuretics or beta-blockers was found ineffective or has been associated with unacceptable adverse effects.

Combination of amlodipine with a diuretic, a beta-blocking agent, or an angiotensin converting enzyme inhibitor has been found to be compatible and showed additive antihypertensive effect.

ANGINA

AmvascTM is indicated for the treatment of myocardial ischemia, only if the latter is due to fixed obstruction (stable angina) and/or vasospasm / vasoconstriction (prinzmetal's or variant angina) of coronary vasculature.

AmvascTM can be used alone, as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta-blockers.

CONTRAINDICATIONS:

Amlodipine is contraindicated in patients with hypersensitivity to the drug or other dihydropyridines, and in patients with severe hypotension (less than 90 mmHg systolic).

Amlodipine is contraindicated in unstable angina and for 8 days after myocardial infarction.

ADVERSE REACTIONS:

Headache, edema, dizziness, fatigue, flushing and nausea palpitations, rash, pruritus, impotence, muscle cramps, weakness, dyspepsia.

PRECAUTIONS:

Use in elderly

Amlodipine, used at similar doses in elderly or younger patients, is equally well tolerated.

Use in renal failure

Amlodipine, may be used in renal failure patients at normal doses. Amlodipine is not dialysable.

Use in patients with impaired hepatic function

As with other calcium channel blockers; amlodipine half life is prolonged in patients with impaired hepatic function. The drug should therefore be administered with caution in these patients.

Use in pregnancy & nursing mothers

Amlodipine should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus. Amlodipine should not be given to nursing mothers.

DRUG INTERACTIONS:

Amlodipine has been safely administered with thiazide diuretics, alpha blockers, beta blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerin, NSAIDs, antibiotics and oral hypoglycemic drugs.

Pharmacokinetic interaction studies with amlodipine in healthy volunteers have indicated that cimetidine did not alter the pharmacokinetics of amlodipine. Amlodipine did not change warfarin-induced prothrombin response time. Amlodipine does not significantly alter the pharmacokinetics of cyclosporin. Amlodipine did not change serum digoxin levels or digoxin renal clearance.

DOSAGE AND ADMINISTRATION:

One 5 mg capsule daily, if required, daily dosage may be increased to 10 mg in a single dose, AmvascTM can be taken with, before or after meals.

PACKS:

2.5 mg capsules, box of 30 capsules.

5 mg capsules, box of 30 capsules.

10 mg capsules, box of 30 capsules.

STORAGE:

When stored at room temperature (15° - 25° C), AmvascTM capsules will retain full potency until the expiry date shown on the pack. Keep out of the reach of children.

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



CVD Medicine

AmvascTM is a quality product manufactured by:



جمجوم فارما
Jamjoom Pharma

P.O.Box 6267 Jeddah - 21442- Saudi Arabia

32171061 - Rev. 00/23-05-07