

Antihypertensives

Amlotrust -2.5 Tablets

Amlotrust - 5 Tablets

Composition

Amlotrust-2.5

Each uncoated tablet contains Amlodipine Besylate equivalent to Amlodipine 2.5 mg

Amlotrust-5

Each uncoated tablet contains Amlodipine Besylate equivalent to Amlodipine 5 mg

Description

Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow calcium channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells.

Amlodipine is a peripheral vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

The precise mechanisms by which amlodipine relieves angina have not been fully delineated.

Indications

Amlotrust is indicated for hypertension, chronic stable angina and vasospastic angina (Prinzmetal's or variant angina). **Amlotrust** may be used as monotherapy or in combination with other antihypertensive or antianginal drugs.

Dosage and Administration

Hypertension

Initial dose of 5 mg once daily, with a maximum dose of 10 mg once daily.

Small, fragile or elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding amlodipine to other anti-hypertensive therapy.

Chronic, stable or vasospastic angina

5-10 mg with a lower dose (2.5 mg) in the elderly and in patients with hepatic insufficiency.

Co-administration with other antihypertensives and/or antianginal drugs

Amlodipine has been safely administered with thiazides, ACE inhibitors, beta-blockers, long acting nitrates and/or sublingual nitroglycerin.

Contraindications

Amlodipine is contraindicated in patients with known hypersensitivity to amlodipine.

Warnings and Precautions

DRUG INTERACTIONS

Digoxin: Amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers.

Cimetidine: Co-administration with cimetidine did not alter the pharmacokinetics of amlodipine.

Warfarin: Co-administration with warfarin did not change the warfarin prothrombin response time.

In clinical trials, amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs.

PREGNANCY

Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

NURSING MOTHERS

It is not known whether amlodipine is excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while amlodipine is administered.

PAEDIATRIC USE

Safety and effectiveness of amlodipine in children have not been established.

PATIENTS WITH HEPATIC FAILURE

Amlodipine is extensively metabolised by the liver and the plasma elimination half-life is prolonged in patients with impaired hepatic function. Caution should be exercised when administering amlodipine to patients with severe hepatic impairment (See also Dosage and Administration).

BETA-BLOCKER WITHDRAWAL

Amlodipine is not a beta-blocker and therefore gives no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be by gradual reduction of the dose of beta-blocker.

OTHERS

Rarely patients, particularly those with severe obstructive coronary artery disease, have developed increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated.

Since the vasodilation induced by amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration of amlodipine. Nonetheless,

caution should be exercised when administering amlodipine as with any other peripheral vasodilator particularly in patients with severe aortic stenosis.

All calcium channel blockers should be used with caution in patients with heart failure.

Side Effects

Amlodipine is well tolerated. Side effects include headache, edema, fatigue, somnolence, nausea, abdominal pain, flushing, palpitations and dizziness.

Less commonly observed are pruritus, rash, dyspnea, asthenia, muscle cramps and dyspepsia. Rarely, myocardial infarction and chest pain have been reported.

Presentation

Amlotrust-2.5 Blister pack of 10 tablets

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