



Amlodipine and Atenolol Film coated tablet

DESCRIPTION

Sidoplus® is the fixed dose combination of Amlodipine and Atenolol. 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. It is a peripheral vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Atenolol is a cardio-selective beta-blocker. It does not possess any membrane-stabilizing or partial agonist action. The cardio-selectivity is dose-related. Atenolol causes a reduction in blood pressure by lowering cardiac output, decreasing the plasma renin activity and sympathetic outflow from CNS. Atenolol also causes a reduction in myocardial oxygen demand by virtue of its negative inotropic and negative chronotropic effects.

INDICATIONS

Sidoplus® is indicated for the treatment of hypertension, chronic stable angina and vasospastic angina (Prinzmetal's or Variant angina).

DOSAGE AND ADMINISTRATION

The recommended dosage is one tablet daily. If necessary, the dosage may be increased to two tablets daily. The dosage however should be individualized.

CONTRAINDICATIONS

Hypersensitivity to either component, sinus bradycardia, second and higher degrees of heart block, cardiogenic shock, hypotension, congestive heart failure, poor left ventricular function.

USE IN PREGNANCY & LACTATION

The combination should preferably not be given during pregnancy. However it can be used in pregnancy only if the expected benefit outweighs the potential foetal risk. It should not be used by nursing mothers. If its use is considered necessary, breast-feeding should be stopped.

WARNINGS

Amlodipine & Atenolol combination should be used with caution in patients with renal impairment (creatinine clearance less than 30 ml/min) and in patients with severe liver damage

PRECAUTIONS

Hypotension: Excessive fall of blood pressure can occur in some patients especially the elderly.

Aggravation of angina: 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.

Drug withdrawal: Since coronary heart disease may exist without being recognised, patients should be warned against stopping the drug suddenly. Any discontinuation should be gradual and under observation.

Bronchospasm: The combination should be used with caution in patients with airway obstruction.

DRUG INTERACTIONS

Disopyramide: Atenolol reduces the clearance of disopyramide by 20%. Additive negative inotropic effects on the heart may be produced.

Ampicillin: At doses of 1 g and above may reduce Atenolol levels.

Oral antidiabetics and insulin: Beta-blockers may decrease tissue sensitivity to insulin and inhibit insulin secretion e.g. in response to oral antidiabetics. Atenolol has less potential for these actions. The heart rate may not be reliable as an early warning of hypoglycemia.

SIDE EFFECTS

The combination of Amlodipine and Atenolol is well tolerated. Side effects include headache, palpitations, flushing, edema, depression, dizziness, dyspepsia, dyspnoea, muscle cramps, fatigue, cold extremities and bradycardia.

OVERDOSAGE

Though not documented, hypotension and less frequently congestive cardiac failure may occur in cases of overdosage. Unabsorbed drugs may be removed by gastric lavage or administration of activated charcoal. Symptomatic treatment is suggested.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Sidoplus® 25 tablet : Box containing 4 strips of 10 tablets each. Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Atenolol BP 25 mg.

Sidoplus® 50 tablet : Box containing 5 strips of 10 tablets each. Each film coated tablet contains Amlodipine Besilate BP equivalent to Amlodipine 5 mg and Atenolol BP 50 mg.

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Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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M/PM00447 V04