



AMLODIPINE

CARDIVASC

5 mg & 10 mg Tablet

CALCIUM CHANNEL BLOCKER



FORMULATION

Each tablet contains:

Amlodipine (as besilate), USP 5 mg

Amlodipine (as besilate), USP 10 mg

PRODUCT DESCRIPTION

Amlodipine as besilate (Cardivasc) 5 mg Tablet: White to off-white, round, biconvex tablet, bisected on one side, with "YSS" on the other side

Amlodipine as besilate (Cardivasc) 10 mg Tablet: White to off-white, round, flat tablet, bisected on one side, with "YSS" on the other side

PHARMACODYNAMICS

Amlodipine inhibits calcium ion from entering the "slow channels" or select voltage-sensitive areas of vascular smooth muscle and myocardium during depolarization, producing a relaxation of coronary vascular smooth muscle and coronary vasodilation; increases myocardial oxygen delivery in patients with vasospastic angina.

PHARMACOKINETICS

Amlodipine is well absorbed after oral doses with peak blood concentrations occurring after 6 to 12 hours. The bioavailability varies but is usually about 60 to 65%. Amlodipine is reported to be about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half-life of 35 to 50 hours and steady-state plasma concentrations are not achieved until after 7 to 8 days of use. Amlodipine is extensively metabolised in the liver; metabolites are mostly excreted in urine together with less than 10% of a dose as unchanged drug. Amlodipine is not removed by dialysis.

INDICATIONS

Amlodipine (Cardivasc) is indicated for the management of hypertension and prophylaxis of angina.

DOSAGE AND ADMINISTRATION

Amlodipine is given orally. The dose for both hypertension and angina, initially 5 mg once daily, increased if necessary, to maximum dose of 10 mg once daily or as prescribed by the physician.

Elderly patients

Lower initial dose may be used.

Patients with hepatic impairment

The clearance of amlodipine is reduced in patients with hepatic impairment and lower doses should be considered; an initial dose of 2.5 mg once daily.

CONTRAINDICATIONS

Patients who have shown hypersensitivity to Amlodipine and other dihydropyridines.

PRECAUTIONS

Amlodipine should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor, and in those with heart failure since deterioration of heart failure has been noted.

Amlodipine half-life is prolonged in patients with hepatic impairment, may need dose reduction.

PREGNANCY AND LACTATION

Amlodipine safety in pregnancy has not been established. Used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus, but if possible avoid during pregnancy.

It is not known whether amlodipine is excreted in human milk. However, amlodipine safety in infants has not been established. Advise not to be given to nursing mothers.

DRUG INTERACTIONS

Antibacterials

The macrolide antibacterials are inhibitors of the cytochrome P450 isoenzyme CYP3A4 and may inhibit the metabolism of calcium-channel blockers like amlodipine.

Antiepileptics

The effects of dihydropyridine calcium-channel blockers (e.g. amlodipine) may be reduced by enzyme-inducing antiepileptics such as carbamazepine, phenobarbital, and phenytoin.

Antifungals

Azole antifungals inhibit cytochrome P450 enzyme system and may therefore interfere with metabolism of calcium-channel blockers (e.g. amlodipine).

Antivirals

The HIV-protease inhibitors are known to inhibit the cytochrome P450 isoenzyme CYP3A4 and may therefore interfere with the metabolism of calcium-channel blockers (e.g. amlodipine).

Digoxin

The mechanism of interaction between calcium-channel blockers and digoxin is not completely understood but appears to be related to decreased renal and nonrenal clearance of digoxin. The pharmacodynamic effects of digoxin and calcium-channel blockers (e.g. amlodipine) may also be additive.

Grapefruit juice

Grapefruit juice inhibits the cytochrome P450 isoenzyme CYP3A4, particularly in the intestinal wall, and has shown to increase markedly the bioavailability of orally-administered calcium-channel blockers.

The interaction may be less significant with amlodipine that have a higher bioavailability.

Immunosuppressants

Ciclosporin concentrations have been reported to increase or to remain unchanged with amlodipine. Use of amlodipine with ciclosporin may exacerbate the problem of gingival hyperplasia.

Beta-adrenergic blockers

Beta-adrenergic blockers have additive effects and must be used with caution to prevent excessive myocardium depression.

Antihypertensive drugs

Antihypertensive drugs such as prazosin, methyldopa, clonidine have additive effects and can cause dangerous hypotensive effects

Non-depolarizing muscle relaxants

Action may be increased

Cimetidine

Decreases the first pass effects of calcium channel blockers

ADVERSE EFFECTS

Abdominal pain, nausea, palpitation, flushing, edema, headache, dizziness, sleep disturbances, fatigue

Less commonly: Gastrointestinal disturbances, dry mouth, taste disturbances, hypotension, syncope, chest pain, dyspnea, rhinitis, mood changes, tremor, paraesthesia, urinary disturbances, impotence, gynaecomastia, weight changes, myalgia, visual disturbances, tinnitus, pruritus, rashes, alopecia, purpura, and skin discoloration.

Very rarely: Gastritis, pancreatitis, hepatitis, jaundice, cholestasis, gingival hyperplasia, myocardial infarction, arrhythmias, vasculitis, coughing, hyperglycemia, thrombocytopenia, angioedema, and urticaria.

OVERDOSE AND TREATMENT

Symptoms: Primary cardiac symptoms of overdosage include marked and prolonged hypotension and bradycardia, both of which may result in decreased cardiac output. Noncardiac symptoms include confusion, stupor, nausea, vomiting, metabolic acidosis, and hyperglycemia.

Treatment: If the patient is seen shortly after oral ingestion, employ lavage, activated charcoal, and cathartics. Treat other signs and symptoms symptomatically, treatment is supportive. Monitor cardiac and respiratory function; elevate the extremities. Amlodipine is highly protein bound; therefore dialysis is not likely to be of benefit.

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph

Seek advice from a health-care professional at the first sign of any adverse drug reaction.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN**STORAGE CONDITION**

Store at temperatures not exceeding 30°C.

AVAILABILITY

Amlodipine as besilate (Cardivasc) 5 mg Tablet: Aluminum Foil Strip x 10's (Box of 100's)

Amlodipine as besilate (Cardivasc) 10 mg Tablet: Aluminum Foil Strip x 10's (Box of 100's)

Marketing Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
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Manufacturer
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109 North Main Ave., Laguna Technopark, Biñan, Laguna

	REGISTRATION NO.	DATE OF FIRST AUTHORIZATION
Cardivasc 5 mg Tablet	DR-XY36005	June 19, 2009
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