



## Amocal® -AT

Amlodipine + Atenolol

### Description

**Amocal®-AT** is a fixed-dose combination containing Amlodipine and Atenolol. Amlodipine is a dihydropyridine calcium antagonist. Atenolol is a cardio-selective beta-blocker.

### Mode of action

Amlodipine inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle; it has a greater effect on vascular smooth muscle than on cardiac muscle. 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. Amlodipine reduces tone, decreases coronary vasoreactivity and lowers cardiac demand by reducing after load. The cardio-selectivity of Atenolol 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.

### Pharmacokinetics

After oral administration of therapeutic doses of amlodipine besylate, absorption produces peak plasma concentrations between 6 and 12 hours. Absolute bioavailability has been estimated to be between 64 and 90%. It is extensively (about 90%) converted to inactive metabolites via hepatic metabolism with 10% of the parent compound and 60% of the metabolites excreted in the urine. Elimination from the plasma is biphasic with a terminal elimination half-life of about 30-50 hours. Steady state plasma levels of amlodipine besylate are reached after 7 to 8 days of consecutive daily dosing. Absorption of Atenolol after an oral dose is rapid and consistent but incomplete. Approximately 50% of an oral dose is absorbed from the gastrointestinal tract, the remainder being excreted unchanged in the faeces. Only a small amount (6-16%) of atenolol is bound to proteins in the plasma. The elimination half-life of oral atenolol is approximately 6 to 7 hours. Following oral doses of 50 mg or 100 mg, both beta-blocking and antihypertensive effects persist for at least 24 hours.

### Composition

**Amocal®-AT 5/50 Tablet:** Each tablet contains Amlodipine Besilate BP 6.93 mg equivalent to Amlodipine 5 mg and Atenolol BP 50 mg.

### Indications

- Essential hypertension
- Angina pectoris & hypertension as co-existing diseases
- Post Myocardial Infarction
- Refractory angina pectoris where Nitrate therapy has failed.

### Dosage & administration

The recommended dose is one tablet once daily. If necessary, the dosage may be increased to two tablets daily.

### Contraindications

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

### Side effects

The combination of amlodipine and atenolol is well tolerated. Overall side effects include fatigue, palpitation, headache, flushing, edema, dizziness, dyspepsia, dyspnoea, depression, muscle cramps, cold extremities and bradycardia.

### Use in pregnancy & lactation

**Pregnancy:** The combination should be used during pregnancy only if the expected benefit outweighs the potential fetal risk. **Lactation:** The combination should not be used by nursing mothers. If its use is considered necessary, breast-feeding should be stopped.

### Precautions

**Bronchospasm:** The combination should be used with caution in patients with airway obstruction. **Renal impairment:** The combination can be used in patients with renal impairment. However, caution may be necessary if the creatinine clearance is less than 30 ml/min because of possible reduction in the excretion of unchanged atenolol. **Hepatic impairment:** Caution may be necessary in the use of the combination in patients with severe liver damage because of prolongation of the elimination half-life of amlodipine. **Drug withdrawal:** Since coronary heart disease may exist without being recognized, patients should be warned against stopping the drug suddenly. Any discontinuation should be gradual and under observation. **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 interactions

**Disopyramide:** Atenolol reduces the clearance of disopyramide by 20%. Additive negative inotropic effects on the heart may be produced. **Ampicillin:** Doses of 1 gm 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.

### Overdosage

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

### Storage

Store in a cool (Below 25° C temperature) and dry place protected from light.

### Packaging

**Amocal®-AT 5/50 Tablet:** Each carton contains 14X3 tablets in blister pack.



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