

# Amlopin<sup>®</sup>

Tablet

## Amlodipine

### Description

Amlopin<sup>®</sup> (Amlodipine) is a dihydropyridine calcium-channel blocker, with a long duration of action, used for the treatment of hypertension and angina pectoris. Amlopin<sup>®</sup> (Amlodipine) influences the myocardial cells, the cells within the specialized conducting system of the heart, and the cells of vascular smooth muscle. Administration of Amlopin<sup>®</sup> (Amlodipine) results primarily in vasodilation, with reduced peripheral resistance, blood pressure and afterload, increased coronary blood flow and a reflex increase in coronary heart rate. This in turn results in an increase in myocardial oxygen supply and cardiac output.

### Composition

**Amlopin<sup>®</sup> 5** : Each tablet contains Amlodipine (as Besilate) BP 5 mg.

**Amlopin<sup>®</sup> 10** : Each tablet contains Amlodipine (as Besilate) BP 10 mg.

### Indications

Essential hypertension: Amlopin<sup>®</sup> (Amlodipine) is efficacious as monotherapy in the treatment of hypertension. It may be used in combination with other antihypertensive agents.

Angina pectoris: Amlopin<sup>®</sup> (Amlodipine) is indicated for the treatment of chronic stable angina pectoris and is efficacious as monotherapy. It may be used in combination with other antianginal agents.

Vasospastic angina: Amlopin<sup>®</sup> (Amlodipine) is indicated for the treatment of confirmed or suspected vasospastic angina. It may be used as monotherapy or in combination with other antianginal drugs.

### Dosage and Administration

May be taken without regard to meals.

**Hypertension:** Usual dose is 5 mg once daily. Maximum dose is 10 mg once daily. Elderly patients with hepatic insufficiency may be started on 2.5 mg once daily; this dose may also be used when adding Amlopin<sup>®</sup> (Amlodipine) to other antihypertensive therapy.

**Angina (Chronic stable or Vasospastic):** 5 to 10 mg, using the lower dose for elderly and in patients with hepatic insufficiency. Most patients require 10 mg.

### Contraindications

- Hypersensitivity to dihydropyridine derivatives.
- Pregnant woman.

### Adverse effects

The most common adverse effects of amlodipine are associated with the vasodilatory action, such as dizziness, flushing, headache, hypotension and peripheral oedema. Gastrointestinal disturbances, increased micturition frequency, lethargy, eye pain, mental depression and alopecia may also occur. A paradoxical increase in ischaemic chest pain may occur at the start of the treatment and in a few patients excessive fall in blood pressure has led to cerebral or myocardial ischaemia or transient blindness. Rashes, fever and abnormalities in liver function due to hypersensitivity reaction of Amlodipine may occur.

### Drug Interactions

#### Potentially hazardous interactions:

Little or no data are available in patients with markedly impaired cardiac left ventricular function; however, as with other calcium antagonist drugs, the combination of Amlodipine and  $\beta$ -blockers should be avoided in such patients.

#### Other Significant Interactions

**Digoxin**-Absence of any interaction between Amlodipine and Digoxin in healthy volunteers has been documented in a controlled clinical study.

**Cimetidine**-An unpublished clinical study indicated no interaction between, Amlodipine and Cimetidine in healthy volunteers.

**Warfarin**-An unpublished clinical study in healthy volunteers indicates that Amlodipine did not significantly alter the effect of Warfarin on prothrombin time.

**Food**-Food does not alter the rate or extent of absorption of Amlodipine.

### Precautions

Precaution should be taken in patients with hepatic impairment and during pregnancy and breast feeding.

### Supply

**Amlopin<sup>®</sup> 5** : Each box contains 5 x 10 tablets in Alu-Alu blisters.

**Amlopin<sup>®</sup> 10** : Each box contains 3 x 10 tablets in Alu-Alu blisters.

Keep all medicines out of reach of children.

Store in a cool & dry place, protected from light.

\* Further information is available on request.



Manufactured by:

**The ACME Laboratories Ltd.**

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07 1306/02