

## Amlodipine Tablet 5mg



**Codix** Codix Pharma Ltd.

### Composition:

Each uncoated tablet contains:  
Amlodipine Besilate BP  
Eq. to Amlodipine 5mg.  
Excipients q.s.

### Clinical Pharmacology

Amlodipine is a dihydropyridine calcium antagonist 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. Negative inotropic effects can be detected in vitro but such effects have not been seen in intact animals at therapeutic doses. Serum calcium concentration is not affected by amlodipine. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

### Indications

Hypertension, Chronic Stable Angina, Vasospastic Angina (Prinzmetal's or Variant Angina).

### Contraindications

Contraindicated in patients with hypersensitivity to drug substance or any component of the product.

### Drug Interactions

Beta-blockers: May cause increased adverse cardiac effects as a result of myocardial depression.  
Fentanyl: Severe hypotension or increased fluid volume requirements have occurred with similar drug.

### Warning

Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented 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.

### Precautions

Use with caution in patients receiving other peripheral dilators and in those with aortic stenosis, heart failure, or severe hepatic disease.

### Adverse Reactions

Nausea, headache, flushing, hypotension, abdominal pain, peripheral oedema, fatigue, dizziness, palpitation, rash.

### Overdose

Gastric lavage may be of benefit. Gross over dose could result in excessive peripheral vasodilation, resulting in marked and probably prolonged systemic hypotension. Clinically significant hypotension due to COD-AMLODIPINE<sup>2</sup> 5 over dose requires active cardiovascular support. Intravenous calcium gluconate may be of benefit in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit. TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

### Dosage & Administration

Adults: The usual initial antihypertensive oral dose of amlodipine is 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 antihypertensive therapy.

### Identification

White to off-white coloured, round, flat, one side break line and other side plain uncoated tablets.

### Presentation

10 X 10 Tablets in Alu Alu Blister pack. (Box of 100 Tablets)

3 X 10 Tablets in Alu Alu Blister pack. (Box of 30 Tablets)

### Storage Condition

Store in the original package. Do not Store above 30°C. Keep all medicines out of reach & Sight of children.

A Product of: **CODIX PHARMA LTD.** 14,  
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STL/COD-  
02/JUN/00  
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