

# Xelcard<sup>®</sup>

Amlodipine 5 mg and 10 mg tablets

## Composition

**Xelcard<sup>®</sup> 5 mg tablet** : Each tablet contains Amlodipine Besylate BP equivalent to Amlodipine 5 mg.

**Xelcard<sup>®</sup> 10 mg tablet** : Each tablet contains Amlodipine Besylate BP equivalent to Amlodipine 10 mg.

## Description

Amlodipine is a dihydropyridine calcium antagonist, with a long duration of action, used for the treatment of hypertension and angina pectoris.

## Indications

### 1. Hypertension

Amlodipine is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

### 2. Stable Angina

Amlodipine is indicated for the treatment of stable angina. Amlodipine may be used alone or in combination with other antianginal agents.

### 3. Vasospastic Angina

Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy or in combination with other antianginal drugs.

## Dosage and administration

The usual initial antihypertensive oral dose is 5 mg once daily with a maximum dose of 10 mg once daily. Elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily dose and this dose may be used when adding Amlodipine to other antihypertensive therapy. Dosage should be adjusted according to each patient's need. The recommended dose for stable or vasospastic angina is 5-10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency.

## Contraindication

Amlodipine is contraindicated in patients with known hypersensitivity to Amlodipine.

## Pregnancy & Lactation

**Pregnancy:** Amlodipine should not be administered during pregnancy or to women of childbearing potential unless effective contraception is used.

**Lactation:** Amlodipine should not be used by nursing mothers. If its use is considered necessary, breast-feeding should be stopped.

## Precautions

**General :** Since the vasodilatation induced by Amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration of Amlodipine. Nonetheless, caution should be exercised when administering Amlodipine as with any other peripheral vasodilator particularly in patients with severe aortic stenosis.

**Use in Patient with congestive Heart Failure :** Although haemodynamic studies and a controlled trial in class-II-III heart failure patients have shown that Amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction, and clinical symptomatology in general, all calcium channel blockers should be used with caution in patients with heart failure.

**Beta-blocker Withdrawal :** Amlodipine gives no protection against the danger of abrupt beta-blocker withdrawal; any such withdrawal should be gradual reduction of the dose of beta-blocker.

**Hepatic Failure :** Since Amlodipine is extensively metabolized by the liver, so caution should be exercised when administering Amlodipine to patients with hepatic impairment.

## Drug Interactions

No significant drug interaction.

## Side effects

Peripheral oedema may occasionally be severe but is fully reversible. As with other calcium antagonist drugs, peripheral oedema and skin erythema occur in a proportion of patients (5-10%) and facial flushing in 2-5% of patients. Complaint of fatigue was also reported more frequently than in placebo-treated patients.

There is evidence that these effects are more common in patients treated with doses greater than 10 mg daily.

## Overdosage

In humans, experience with intentional overdosage of Amlodipine is limited. If massive overdosage occurs, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential.

## Commercial Pack

**Xelcard<sup>®</sup> 5 :** Box containing 3x10's tablets in blister pack.

**Xelcard<sup>®</sup> 10 :** Box containing 3x10's tablets in blister pack.

## STORAGE

Store in a cool and dry place below 30°C. Protect from light and moisture.

Medicine: Keep out of reach of children



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