

# AXCEL AMLODIPINE TABLET

Amlodipine (5mg & 10mg)

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## **WHAT AXCEL AMLODIPINE TABLET IS USED FOR**

Axcel Amlodipine Tablet is indicated for the first line treatment of hypertension (high blood pressure) and can be used as the sole agent to control blood pressure in the majority of patients. Besides, it is indicated for the first line treatment of myocardial ischemia (decrease of blood flow in the blood vessel which leads to reduced oxygen supply in the heart) whether due to fixed obstruction (stable angina) and/or vasospasm / vasoconstriction (a condition that can lead tissue ischemia and tissue death) or coronary vasculature (the arrangement or distribution of blood vessels in the heart).

## **HOW AXCEL AMLODIPINE TABLET WORKS**

Amlodipine works by relaxing the human blood vessels so that the blood passes through them more easily. Hence, the blood pressure is reduced.

## **BEFORE YOU USE AXCEL AMLODIPINE TABLET**

### **When you must not use it**

Do not take Axcel Amlodipine Tablet if:

- If you are allergic or hypersensitive to dihydropyridines, amlodipine or any of the inert ingredients.

### **Before you start to use it**

Tell your doctor if:

- If you have impaired liver function or renal failure.
- If you are pregnant or lactating.

### **Taking other medicines**

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Amlodipine Tablet.

## **HOW TO USE AXCEL AMLODIPINE TABLET**

### **How much to use**

For oral administration only.

For both hypertension and angina the usual initial dose is 5mg amlodipine once daily which may be increased to a maximum dose of 10mg depending on the individual patient's response. No dose adjustment of amlodipine is required upon concomitant administration of thiazide diuretics, beta-blockers, and angiotensin converting enzyme inhibitors.

### *Use in the Elderly*

Normal dosage regimens are recommended. Amlodipine, used at similar doses in elderly or younger patients, is equally well tolerated.

### *Use in Children*

Safety and effectiveness of amlodipine in children have not been established.

### *Use in Patients with Impaired Hepatic Function*

Dosage recommendations have not been established. The drug should therefore be administered in caution.

### *Use in Renal Failure*

Amlodipine may be used in such patients at normal doses. Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment. Amlodipine is not dialyzable.

### **When to use it**

Your doctor will decide when it is appropriate for you to take Axcel Amlodipine Tablet.

### **How long to use it**

- Follow any recommendations and advices from your doctor or pharmacist.

### **If you forget to use it**

- Do not double up the dosage as Axcel Amlodipine Tablet may give you unacceptable side effects.

### **If you use too much (overdose)**

- If you have accidentally use too much Axcel Amlodipine, please go to the nearest hospital immediately to seek medical treatment. Please bring along the package/box/remaining tablet to show to the doctor. Your doctor may administer activated charcoal to you to decrease amlodipine absorption.

## **WHILE YOU ARE USING IT**

### **Things you must do**

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Amlodipine Tablet according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

### **Things you must not do**

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

### **Things to be careful of**

- Clinical experience with amlodipine indicates that it is unlikely to impair the ability to drive or use machinery. However, please be careful when driving or using machinery before you know this tablet could affect you.

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## **SIDE EFFECTS**

Like all medicines, Axcel Amlodipine Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

- Headache
- Edema
- Fatigue
- Abdominal pain
- Nausea
- Flushing
- Somnolence (drowsiness/lethargy)
- Palpitation (abnormality of heartbeat)
- Dizziness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers -> Reporting).

## **STORAGE AND DISPOSAL OF AXCEL AMLODIPINE TABLET**

### **Storage**

Keep Axcel Amlodipine Tablet out of reach of children.  
Store below 30°C. Keep container well closed and protect from light.

### **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **PRODUCT DESCRIPTION**

### **What it looks like**

Axcel Amlodipine-5 Tablet  
White, rectangular tablet, 8.8mm in length and 6.2mm in width, with KOTRa engraved on one side and score line on the opposite line.

Axcel Amlodipine-10 Tablet  
White, rectangular tablet, 11.6mm in length and 8.3 mm in width, with KOTRa engraved on one side and score line on the opposite line.

## **Ingredients**

*Active Ingredient (s):*  
Amlodipine Besylate

*Inactive Ingredients:*

Dibasic Calcium Phosphate Anhydrous, Microcrystalline Cellulose, Sodium Starch Glycolate and Magnesium Stearate.

## **MAL Number**

Axcel Amlodipine-5 Tablet  
MAL11120003A

Axcel Amlodipine-10 Tablet  
MAL11120002A

## **MANUFACTURER AND PRODUCT REGISTRATION HOLDER**

KOTRA PHARMA (M) SDN BHD  
No. 1, 2 & 3, Jalan TTC 12,  
Cheng Industrial Estate,  
75250 Melaka, Malaysia.

## **DATE OF REVISION**

12/08/2014