

CAMLODIN[®] TABLET

Amlodipine Besilate 5 mg & 10 mg

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1. What CAMLODIN[®] TABLET is used for

CAMLODIN[®] TABLETS are used for:

- High blood pressure
- Various types of angina except for unstable angina

Amlodipine may be used to treat angina on its own or together with other medicines.

2. How CAMLODIN[®] TABLET works

Amlodipine belongs to a group of medicines known as calcium-channel blockers (calcium antagonists). Calcium-channel blockers lower blood pressure by relaxing the blood vessel walls. They also have an effect on the heart, so that they can be used for angina (angina pectoris).

3. Before you use CAMLODIN[®] TABLET

When you must not use it

- If you are allergic to amlodipine or similar calcium-channel blockers (the so-called dihydropyridine derivatives), or to any of the other ingredients.
- If you have very low blood pressure.
- If you are suffering from shock (a very severe lowering of blood pressure by which you become unconscious).
- If you suffer from unstable angina pectoris.

If you are not sure whether any of the above applies to you, ask your pharmacist or your doctor.

Before you start to use it

Ask your doctor and take special care with amlodipine tablets

- If you have heart failure.
- If you have liver problems; amlodipine must be used very carefully because the required dosage is not known exactly in this situation.
- If you are under 18 years of age; amlodipine should not be given to children because there is not enough experience with its use in children.

Pregnancy

There is very little information on whether it is harmful to take amlodipine during pregnancy. Amlodipine should only be used during pregnancy if your doctor decides that it is absolutely necessary. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

There is no information on the use of amlodipine while breast-feeding. You are advised not to breastfeed when using amlodipine. Ask your doctor or pharmacist for advice before taking any medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking other medicines or if you have recently taken other medicines. This includes medicines that you can buy without a prescription.

4. How to use CAMLODIN[®] TABLET

How much to use

Always take amlodipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The dose is decided by your doctor. Take the tablets by mouth with plenty of liquid, for example a glass of water.

Adults

Starting dose for high blood pressure and angina: 5 mg once a day.

The dose may be increased to a maximum of 10 mg once a day.

Children

Amlodipine should not be used in children.

Elderly

There is no special dosage for the elderly; however, care must be taken when the dose is increased.

If you have kidney problems

If you have kidney problems, the dose does not need to be changed. Amlodipine cannot be removed from the blood by dialysis (artificial kidney).

If you go for kidney dialysis, amlodipine should be taken with particular caution.

If you have liver problems

The exact dose needed for patients with liver problems has not been determined. If you have liver problems, amlodipine should be used very carefully.

If you think that amlodipine tablets do not work or have a too potent effect, discuss this with your doctor or pharmacist.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Your doctor has told you for how long you should take amlodipine. If you stop the treatment suddenly, your symptoms may come back. Do not stop the treatment earlier than agreed without discussing this with your doctor or pharmacist.

Continue taking CAMLODIN[®] TABLET for as long as your doctor recommends.

If you forget to use it

If you have forgotten to take a tablet, you can still take it up to 12 hours after you usually take your tablet. If it is more than 12 hours after the time that you should have taken the tablet, you should not take the missed dose and you should

take the next tablet at the usual time. Never take a double dose of Amlodipine Tablets to make up for the dose that you have missed.

If you use too much (overdose)

Contact your doctor or pharmacist immediately.

The person concerned should be made to lie down. Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed, problems with breathing, having to urinate very often.

5. While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking CAMLODIN[®] TABLET.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give CAMLODIN[®] TABLET to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Consult your doctor if you:

- have heart failure
- have liver impairment
- are elderly

6. Side effects

The most commonly observed side effects are:

Autonomic Nervous System: flushing

Body as a Whole: fatigue

Cardiovascular, General: edema

Central & Peripheral Nervous System: dizziness, headache

Gastrointestinal: abdominal pain, nausea

Heart Rate/Rhythm: palpitations

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (Consumers →Reporting).

7.Storage and Disposal of CAMLODIN[®] TABLET

Storage

Keep out of the reach and sight of children. Store below 30°C in a dry place. Do not use CAMLODIN tablets after the expiry date stated on the label / carton. The expiry date refers to the last day of that month.

Disposal

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

8. Product description

What it looks like

Camlostin[®] 5 Tablet: A yellow color round slightly biconvex tablet having break-line on one side.

Camlostin[®] 10 Tablet: A blue color round, flat tablet engraved "SPL" on one side.

Ingredients

- Active ingredient :
Amlodipine Besilate. Each tablet contains 5 mg and 10 mg of Amlodipine.
- Inactive ingredients:
Pregelatinized starch,
Microcrystalline cellulose, Lactose,
FD & C Blue No.1 (for Camlostin 10mg), FDC Yellow (for Camlostin 5mg), Purified water and magnesium stearate.

NO MAL:

1.Camlostin 5 Tablet: MAL07122772A

2.Camlostin 10 Tablet: MAL07122773A

Manufacturer

Square Pharmaceuticals Limited,
Square Road, Salgaria, Bangladesh.

Product Registration Holder

Medispec (M) Sdn Bhd,
No. 55 & 57, Lorong Sempadan 2,
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11400 Ayer Itam, Penang,
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Date of revision

16/02/14