COVASC®

Amlodipine Besylate (5 mg, 10 mg)

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What Covasc is used for

Covasc is used to lower high blood pressure (hypertension). Covasc is also used to treat angina pectoris. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.

Ask your doctor if you have any questions about why Covasc has been prescribed for you. Your doctor may have prescribed it for another purpose.

How Covasc works

Covasc belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. They work by widening your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. Calcium channel blockers do not change the amount of calcium in your blood or bones.

Before you use Covasc

- *When you must not use it*

Do not take Covasc if you have ever had an allergic reaction to:

- Covasc, or any other medicine containing amlodipine
- Other calcium channel blockers such as those listed below: felodipine, nifedipine, or lercanidipine.
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

Do not give this medicine to anyone else.

Pregnancy and lactation

Tell your doctor if you are pregnant or plan to become pregnant. This medicine may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not take Covasc if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.
It is not known if the active ingredient in Covasc passes into breast milk or if your baby may be affected.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- *Before you start to use it*

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease such as heart failure
- liver problems

If you have not told your doctor about any of the above, tell him/her before you start taking Covasc.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including all medicines, vitamins, herbal supplements or natural therapies that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Covasc. These include:

- other medicines used to treat angina, such as diltiazem
- some antibiotics, such as erythromycin or rifampicin
- some antifungals, such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection, such as ritonavir
- St John's Wort
- grapefruit or grapefruit juice

These medicines may be affected by Covasc or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking Covasc.

How to use Covasc

- *How much to use*

Your doctor will tell you how much Covasc to take.

The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

Usual adult and adolescent dose:

5 mg each day or your doctor may increase this to 10 mg each day.

Your doctor may prescribe another dose of Covasc depending on your condition and how you respond to this medicine.

Usual children dose:

There is not enough information to recommend the use of this medicine in children.

- *When to use it*

Take your medicine at about the same time each day, either morning or evening.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. Covasc can be taken with or without food.

- *How long to use it*

You must take Covasc every day. Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not miss any doses and do not stop taking the medicine even if you feel better.

Missing doses may make your symptoms worse.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is less than 12 hours before your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many tablets, you may feel dizzy, lightheaded or faint and have an irregular heartbeat.

While you are using it

- *Things you must do*

Take Covasc exactly as your doctor has prescribed.

Tell your doctor if your condition returns or becomes worse after your dose of Covasc has been reduced or treatment has been stopped.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Covasc, especially if you are being started on any new medicines.

- *Things you must not do*

Do not give Covasc to anyone else, even if they have a similar condition to you.

Do not stop taking Covasc or lower the dosage, without checking with your doctor or pharmacist.

- *Things to be careful of*

Check with your doctor or pharmacist before drinking alcohol while you are taking this medicine.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Covasc can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Covasc.

These following are common side effects of Covasc:

- swelling of the ankles, feet, face or hands
- headache
- dizziness
- flushing
- palpitations
- tiredness
- drowsiness or sleepiness
- stomach pain or nausea

These following are serious side effects of Covasc. You may need urgent medical attention:

- changes in heart beat either fast or slow
- chest pain
- dizziness or lightheadedness on standing up from a sitting or lying position
- shortness of breath
- symptoms of allergy such as skin rash and/or itching
- symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark colored urine

If you are 65 years or older, you should be especially careful while taking Covasc. Report any side effects promptly to your doctor.

Some people in this age group may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Covasc

- *Storage*

Keep Covasc in a cool dry place where the temperature stays below 30°C. Protect from light.

Keep your tablet in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Do not store Covasc or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and a half meters above the ground is a good place to store medicines.

- *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*

Covasc are available in two strengths:

Covasc Tablet 5 mg:
White to off white, shield shape tablet, marked "COV" on one side and scored on the other side

Covasc Tablet 10 mg:
White to off white, shield shape tablet, marked "COV" on one side and marked "10" with scored line on the other side

- *Ingredients*
  - Active ingredient

  Covasc Tablet 5 mg:
  - 5 mg amlodipine besylate

  Covasc Tablet 10 mg:
  - 10 mg amlodipine besylate

  - Inactive ingredients
  - Microcrystalline Cellulose
  - Dibasic Calcium Phosphate Anhydrous
  - Sodium Starch Glycolate
  - Magnesium Stearate
- *MAL number(s):*

  Covasc Tablet 5 mg:
  MAL 06061327AZ

  Covasc Tablet 10 mg:
  MAL 08080395AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd.
Lot No. 2 & 4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor, Malaysia.

Product Registration Holder

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