

APROVASC[®] FILM COATED TABLET

Irbesartan/ amlodipine (150/5mg, 150/10mg, 300/5mg, 300/10mg)

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What Aprovasc is used for

Aprovasc contains irbesartan, which belongs to angiotensin-II receptor antagonists and amlodipine, a medicine that belongs to the class of calcium antagonists. They both help to control high blood pressure.

Aprovasc is indicated to treat high blood pressure which is not adequately controlled by a single drug.

How Aprovasc works

Irbesartan works by blocking the effect of angiotensin II. Amlodipine blocks calcium channels at the blood vessels. As a result of both mechanisms, blood vessels relax and blood pressure is lowered.

Before you use Aprovasc

- When you must not use it

Do not take Aprovasc:

- If you are allergic (hypersensitive) to irbesartan, amlodipine, dihydropyridines or any of the other ingredients in the tablet (see section **Product Description**). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are pregnant or planning to become pregnant and breastfeeding.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic stenosis) or unstable angina (a condition in which your heart doesn't get enough blood flow and oxygen. It may lead to a heart attack.)
- If you are suffering from heart failure after a heart attack
- If you have severe low blood pressure (hypotension)

- If you are suffering from type 2 diabetes (also called non-insulin dependent diabetes mellitus) or moderate to severe kidney impairment while you are taking a blood pressure lowering medicine called aliskiren
- If you are having diabetic which has affected your kidney while you are taking a blood pressure lowering medicine (ACE inhibitor)

Pregnancy and breastfeeding

Do not take Aprovasc if you are pregnant or planning to become pregnant. Use during pregnancy has been associated with serious damage to your unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

Your doctor will discuss with you the potential risk of taking Aprovasc during pregnancy.

Tell your doctor if you are breast-feeding or about to start breastfeeding. Amlodipine has been shown to pass into breast milk in small amounts .

- Before you start to use it

Check with your doctor or pharmacist before taking Aprovasc tablets:

- If you are suffering from water/salt loss eg: you are taking a diuretic (a drug increasing the amount of urine) and/or salt restriction, or on hemodialysis.
- If you are being treated for diabetes as you might develop low blood sugar levels during the treatment with Aprovasc. The dose of your diabetes medication may need to be adjusted.
- If you suffer from liver problem.
- If you are suffering from heart failure or narrowing of one or both of the kidney blood vessels (renal artery stenosis).
- If you are elderly and your dose needs to be increased
- If you have/ had psoriasis (chronic inflammatory skin disease) as Aprovasc may worsen your psoriasis.

Older people (aged 65 years and over)

There are no differences of the outcomes of taking Aprovasc for patients aged 65 years or older compared with younger patients.

Children

The use of Aprovasc in children and is not recommended.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This applies to medicines both prescribed and not prescribed by a doctor, especially:

- medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium.
- Certain type of pain killers called non-steroidal anti-inflammatory
- medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). Your doctor may check your kidney function.
- Repaglinide (medication used for lowering blood sugar levels)
- Lithium, a medicine used to treat some types of psychiatric illness. Your blood lithium levels need to be monitored.
- medicines used to treat fungal infections – such as ketoconazole, itraconazole
- medicines used to treat bacterial infections - such as rifampicin, erythromycin, clarithromycin
- heart medicines – such as verapamil, diltiazem
- St. John's wort - also called "hypericum perforatum". This is a medicine used for depression
- dantrolene infusion – for severe body temperature abnormalities
- medicines used to change the way your immune system works – such as tacrolimus, sirolimus, temsirolimus, and everolimus.
- medicines used to protect against transplant rejection (cyclosporine)
- medicine used to control high cholesterol levels (simvastatin)

How to use Aprovasc**- How much to use**

Your doctor will tell you exactly how many tablets of Aprovasc you should take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

The recommended dose of Aprovasc is one film coated tablet per day (no dosage adjustment for elderly and patients with kidney impairment).

- When to use it

Swallow the tablet with a full glass of water. Taking Aprovasc at the same time each day will help you remember when to take your medicine.

Aprovasc may be taken with or without food.

- How long to use it

Continue taking Aprovasc as your doctor tells you.

If you have questions about how long to take Aprovasc, talk to your doctor or your pharmacist.

- If you forget to use it

If you forget to take Aprovasc, take it as soon as you remember and then take your next dose at its usual time.

However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

Symptoms of overdose include low blood pressure; dizziness and tachycardia (a rapid heart rate); noncardiogenic pulmonary edema (excess lung fluid accumulation) causing shortness of breath that may develop up to 24-48 hours after intake. If you have accidentally taken too many tablets of Aprovasc, consult your doctor immediately.

While you are using it**- Things you must do**

- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Aprovasc.
- Always take Aprovasc tablets exactly as your doctor has told you. You should check with your doctor or pharmacist when you are not sure.

- If you become pregnant while you are taking this medicine, tell your doctor immediately.

- Things you must not do

- Do not take more than the recommended dose unless your doctor tells you to. This can increase the risk of side effects.
- Do not give this medicine to anyone else, even if they have the same condition as yours.
- Do not stop taking your medicine unless your doctor tells you to. Stopping your treatment with Aprovasc may cause your disease to get worse.
- Consumption of grapefruit or grapefruit juice with Aprovasc is not recommended as it may result in the drop in blood pressure.

- Things to be careful of**Driving and using machines**

Like many other medicines used to treat high blood pressure, Aprovasc may in rare cases cause dizziness and affect the ability to concentrate. So before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of Aprovasc.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Tell your doctor as soon as possible if you do not feel well while you are taking Aprovasc.

Stop taking Aprovasc and tell your doctor immediately or go to the emergency department of your nearest hospital if you get any of the following serious side effects:

- severe allergic reaction – with symptoms such as rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in

swallowing or breathing, anaphylactic shock.

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions.

The following side effects have been reported for irbesartan and amlodipine combination:

Common (affecting less than 1 in 10 patients): Dizziness; headache; swelling of arms, hands, legs, ankles or feet; fast heartbeat (palpitations); feeling sleepy; dizziness on standing up; swollen gums; protein in urine; increased blood creatine phosphokinase

Uncommon (affecting less than 1 in 100 patients): vertigo; tingling or numbness of the hands or feet; inability to get or maintain an erection; lack of energy; low blood pressure with symptoms such as dizziness, light-headedness; slow heart rate; cough; high levels of nitrogen-containing compounds in the blood (azotemia); high potassium, joint stiffness; joint pain; muscle pain

Not known (no data available on its incidence): skin lesions such as small nodes/lumps or rashes, which may be reddish to purplish in color. They may appear in patches or plaques and cover large part of the body surface area (cutaneous pseudolymphoma); rash that may occur on the skin or sores in the mouth (lichenoid drug eruption)

If any of these affect you severely, tell your doctor.

If any of the side effects get worse, 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 visiting the website npa.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Aprovasc

- Storage

- Keep out of the reach and sight of children.
- Store below 30°C
- Do not use Aprovasc after the expiry date which is stated on the product packaging. 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 how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Aprovasc® film coated tablet 150 mg/5 mg

White, oval shaped film coated tablets with '150/5' debossed on one side and plain on other side.

Aprovasc® film coated tablet 150 mg/10 mg

Pink, oval shaped film coated tablets with '150/10' debossed on one side and plain on other side.

Aprovasc® film coated tablet 300 mg/5 mg

Yellow, oval shaped film coated tablets with '300/5' debossed on one side and plain on other side

Aprovasc® film coated tablet 300 mg/10 mg

White, oval shaped film coated tablets with SNAP TAB scoreline on one side and plain on other side.

- Ingredients:

- *Active ingredient:* The active substances of Aprovasc are Amlodipine Besilate equivalent to Amlodipine (5 mg or 10 mg) and Irbesartan (150 mg or 300 mg).
- *Inactive ingredients:* Cellulose microcrystalline, Croscarmellose Sodium, Hypromellose, Silicon Dioxide, Magnesium Stearate
- *Film coating:* Hypromellose, titanium dioxide (E171), macrogol 400.

- MAL Number:

Aprovasc® film coated tablet 150 mg/5 mg: MAL18086135AZ

Aprovasc® film coated tablet 150 mg/10 mg: MAL18086133AZ

Aprovasc® film coated tablet 300 mg/5 mg: MAL18086132AZ

Aprovasc® film coated tablet 300 mg/10 mg: MAL18086134AZ

Manufacturer

Sanofi-aventis de México, S.A. de C.V.
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Zona Industrial Ocoyoacac,
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Product Registration Holder

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