

PATIENT INFORMATION LEAFLET FOR

CIPLAVASC 5 & CIPLAVASC 10

SCHEDULING STATUS

S3

CIPLAVASC 5 TABLETS

CIPLAVASC 10 TABLETS

Amlodipine besylate

Sugar free

Read all of this leaflet carefully before you start taking CIPLAVASC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CIPLAVASC has been prescribed for you personally, and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CIPLAVASC is and what it is used for
2. What you need to know before you take CIPLAVASC
3. How to take use CIPLAVASC
4. Possible side effects
5. How to store CIPLAVASC
6. Contents of the pack and other information.

1. What CIPLAVASC is and what it is used for

CIPLAVASC contains amlodipine, which belongs to a group of medicines called calcium channel blocker that affects the movement of calcium into the cells of the heart and blood vessels. As a result, it relaxes blood vessels and increases the supply of blood and oxygen to the heart while reducing its workload.

CIPLAVASC is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

CIPLAVASC can be used alone or with other medicines to treat these conditions.

2. What you need to know before you take CIPLAVASC

Do not take CIPLAVASC

- if you are allergic (hypersensitive) to amlodipine, other dihydropyridines (such as nifedipine, felodipine, isradipine) or any of the other ingredients of CIPLAVASC listed in section 6,
- if you have severe low blood pressure (hypotension),
- In combination with grapefruit juice.
- if you are in shock (including cardiogenic shock), that causes your heart to not supply enough blood to your body,
- if you have been diagnosed with narrowing of the aortic valve (aortic stenosis),
- if you have been diagnosed with heart failure after suffering a heart attack (acute myocardial infarction).

Warnings and precautions

Take special care with CIPLAVASC:

- if you are taking other medicines, such as antifungal medicines (ketoconazole, itraconazole) or protease inhibitors used to treat HIV (ritonavir), using these medicines together with CIPLAVASC may decrease your blood pressure even further (see “**Other medicines and CIPLAVASC**”),

- if you have impaired liver or kidney function,
- if you have heart failure problems as there is a small chance that,
- CIPLAVASC may make this condition worse,
- if you have a severe increase in blood pressure (hypertensive crisis).

Use in elderly

The clearance of CIPLAVASC from the body is decreased in the elderly. Therefore, if you are elderly your doctor will start CIPLAVASC therapy at a lower dose and will increase your dose with care.

Use in children

The safety and efficacy of CIPLAVASC in children has not been established.

Other medicines and CIPLAVASC

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

CIPLAVASC may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure. Do not stop taking your other prescription medicines, including any other blood pressure medicines, without talking to your doctor or health care provider first.

If you are taking the following in addition to CIPLAVASC please tell your doctor or pharmacist.

In certain cases, your doctor may want to change the dose, or other precautions may be necessary:

- sublingual nitroglycerin, long-acting nitrates, beta blockers or other antianginal medicine, as these may produce additive effects of lowering the blood pressure and treating the angina,

- protease inhibitors for the treatment of HIV-infection (such as saquinavir, ritonavir, indinavir, nelfinavir),
- azole antifungals for the treatment of fungal infections (such as fluconazole, ketoconazole),
- antibiotics, such as erythromycin or clarithromycin,
- verapamil or diltiazem (for the treatment of high blood pressure, angina, or heart rhythm disorders),
- rifampicin, for the treatment of tuberculosis (TB),
- St John's wort (*hypericum perforatum*), a herbal preparation used for the treatment of mild depression,
- dantrolene intravenous injection, a muscle relaxant used for treating increased body temperature,
- tacrolimus or ciclosporin, immune suppressants,
- simvastatin, for lowering of blood cholesterol levels,
- cholesterol-lowering medicine (simvastatin),
- immunosuppressive medicines (tacrolimus, sirolimus, temsirolimus, everolimus and ciclosporin).

CIPLAVASC with food and drink and alcohol

Do not consume grapefruit or grapefruit juice while taking CIPLAVASC, as this may increase the product's blood pressure-lowering effect, leading to low blood pressure.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Women who are capable of falling pregnant should use contraceptive whilst on taking CIPLAVASC.

CIPLAVASC is excreted in breast milk. The effect of CIPLAVASC in breastmilk to the baby is not known.

Driving and using machines

CIPLAVASC may affect your ability to drive and operate machines. You should take care especially at the beginning of treatment. If you experience dizziness, headache, fatigue or nausea your ability to react may be impaired and you should refrain from driving or operating machines.

3. How to take CIPLAVASC

Do not share medicines prescribed for you with any other person.

Always take CIPLAVASC exactly as your doctor has instructed you. If you are unsure, check with your doctor or pharmacist.

- the initial adult dose is one 5 mg tablet to be taken once a day,
- the dose may be increased to 10 mg to be taken once a day after 10 to 14 days of therapy if there is no improvement,
- you will not need to reduce your CIPLAVASC dose when taking thiazide diuretics, beta-blockers or angiotensin-converting enzyme inhibitors.

Your doctor will tell you how long your treatment with CIPLAVASC will last. Do not stop treatment early because your blood pressure or angina will not be controlled.

If you have the impression that the effect of CIPLAVASC is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPLAVASC than you should

If you have taken too many CIPLAVASC tablets, or if someone takes your medicine by mistake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 to 48 hours after intake.

If you forget to take use CIPLAVASC

Take CIPLAVASC as prescribed. If you miss a dose of CIPLAVASC, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose.

4. Possible side effects

CIPLAVASC can have side effects.

Not all side effects reported for CIPLAVASC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLAVASC, please consult your health care provider for advice.

Check with your doctor as soon as possible or if any of the following side effects occur. If the side effects persist and become bothersome then stop taking CIPLAVASC and tell your doctor immediately or go to the casualty department at your nearest hospital as you may need urgent medical attention.

If any of the following happens, stop taking CIPLAVASC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions with itching, rash, swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- any blistering skin rash,
- inflammation of the liver (hepatitis) with or without yellowing of the skin and eyes (jaundice),
- these are all very serious side effects. If you have them, you may have had a serious reaction to CIPLAVASC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- swelling of hands and feet / ankles, pounding heartbeat,
- difficult breathing,
- patches of purplish discoloration on the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, as these symptoms may be due to abnormal blood cell and platelet counts,
- pins and needles, damage to the peripheral nerves marked by weakness, numbness and pain, usually in your hands and feet,
- loss of consciousness / fainting, heart attack, irregular beating of the heart (including slow or fast heartbeat),
- low blood pressure (including a sudden fall in blood pressure that occurs when you stand up), inflammation of a blood vessel, sometimes with a skin rash (vasculitis),
- inflammation of the pancreas (pancreatitis) or inflammation of the lining of the stomach (gastritis), causing stomach pain, tenderness when touching the abdomen, upset stomach, bloating, nausea and vomiting.

Tell your doctor if you notice any of the following:

Frequent side effects

- fizziness, headache, drowsiness/sleepiness,
- flushing/red coloration of the skin,
- muscle cramps,
- increased tightness of muscle tone, tremor.

Less frequent side effects

- increased blood sugar levels, causing blurry vision, frequent urination and fatigue,
- depression, sleeplessness, mood changes (including anxiety), confusion,
- distortion of the sense of taste (taste perversion),
- ringing or buzzing sound in the ears,
- visual disturbances, including double vision,
- coughing, runny nose,
- nausea, stomach pain, indigestion, altered bowel habits including diarrhoea/loose stools and constipation,
- vomiting, dry mouth, thickening of the gums,
- raised liver enzymes,
- hair loss, skin discolouration, increased sweating, itching, rash, hives, redness and scaling/crusting of the skin (exfoliative dermatitis), skin rash on areas exposed to sunlight (photosensitivity), red patches on skin
- pain in the joints, back pain, pain in the muscles,
- increased urinary frequency, increased urination during the night,
- impotence, enlargement of breast tissue in men,
- fatigue, lack or loss of strength/energy,
- pain, weight increase/decrease, chest pain, general feeling of being unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website , or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CIPLAVASC.

5. How to store CIPLAVASC

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep the blister strips in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example: Toilets.

6. Contents of the pack and other information

What CIPLAVASC contains

Each CIPLAVASC 5 tablet contains amlodipine besylate equivalent to 5 mg active amlodipine base.

Each CIPLAVASC 10 tablet contains amlodipine besylate equivalent to 10 mg active amlodipine base.

The other inactive ingredients are colloidal silicon dioxide (Aerosil 200), dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose (Avicel pH 102) and sodium starch glycolate.

What CIPLAVASC looks like and contents of the pack

CIPLAVASC 5: White, circular, flat, bevelled, uncoated tablet with '5'

debossed on one face and central break line on the other.

CIPLAVASC 10: White, circular, flat, bevelled, uncoated tablet with '10'

debossed on one face and central break line on the other.

CIPLAVASC 5 and CIPLAVASC 10 are both available in PVC/aluminium blister foil strips of 14 or 10 tablets packed in a carton each containing 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information and the translated Patient Information Leaflet, scan the QR Code below:

PLACE HOLDER:

The QR Code to be generated
and included after approval.