PATIENT INFORMATION LEAFLET

Information for the Patient about

CIPLAVASC 5 and

CIPLAVASC 10 (Tablets)

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CIPLAVASC 5 containing 5 mg **amlodipine** (Tablets)

CIPLAVASC 10 containing 10 mg **amlodipine** (Tablets)

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 or your pharmacist.**
- **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 CIPLAVASC CONTAINS:

The active substance is amlodipine.

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 IS USED FOR:

CIPLAVASC is a calcium channel blocker. **CIPLAVASC** affects the movement of calcium into the cells of the heart and blood vessels. As a result, **CIPLAVASC** relaxes blood vessels and increases the supply of blood and oxygen to the heart while reducing its workload.

CIPLAVASC is a therefore a vasodilator and hypotensive medicine and is used to treat angina (chest pain) and high blood pressure.

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**.
- Have severe low blood pressure (hypotension).
- Are in shock (including cardiogenic shock), that causes your heart to not supply enough blood to your body.
- Have been diagnosed with narrowing of the aortic valve (aortic stenosis).
- Have been diagnosed with heart failure after suffering a heart attack (acute myocardial infarction).

The safety of **CIPLAVASC** in pregnancy and breastfeeding has not been established (see **"Pregnancy and breastfeeding"**).

Take special care with CIPLAVASC:

Tell your doctor if you have any of the following as you may then require a lower dose or special monitoring:

- 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).
- If you have been diagnosed with porphyria.

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.

Taking CIPLAVASC with food and drink:

CIPLAVASC can be taken without regard to meals. Do not consume grapefruit or grapefruit juice while taking **CIPLAVASC**, as it may increase the blood pressure lowering effect of **CIPLAVASC**, leading to low blood pressure.

Pregnancy and breastfeeding:

The safety of **CIPLAVASC** in pregnancy and breastfeeding has not been established. It is not known whether **CIPLAVASC** is excreted in breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CIPLAVASC.

Driving and using machinery:

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.

Taking other medicines with CIPLAVASC:

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

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.
- Do not consume grapefruit or grapefruit juice while taking **CIPLAVASC**, as it may increase the blood pressure lowering effect of **CIPLAVASC**, leading to low blood pressure.
- If your doctor prescribes it, you may use a sublingual nitroglycerin to abort an acute angina attack while taking **CIPLAVASC**.
- You may use nitrate medication as an angina prophylaxis while taking **CIPLAVASC**.
- **CIPLAVASC** will not compensate for the sudden withdrawal of beta blockers. If your doctor instructs you to stop taking your beta blocker, you will be advised not to stop it abruptly, but to reduce the dose gradually.
- If your doctor prescribes it, you may use thiazide diuretics (“water tablets”), non-steroidal anti-inflammatory medicines (such as indomethacin, ibuprofen), antibiotics, oral blood sugar lowering medicines, atorvastatin (for lowering of

blood cholesterol levels), digoxin (for treatment of heart failure), warfarin (a blood thinner) or phenytoin (for the treatment of epilepsy) while taking **CIPLAVASC**.

- Tell your doctor if you are using any other over-the-counter (OTC) medicine since they may tend to increase your blood pressure.

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. You should check with your doctor or pharmacist if you are unsure.

- 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 – 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:

In the event of an overdosage (if you take too many tablets), or if someone else has taken your medicine by mistake, you, or this other person, may experience prolonged low blood pressure.

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.

If you forget to take 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.

Effects when treatment with CIPLAVASC is stopped:

If you will not be taking **CIPLAVASC** any longer, consult your doctor for advice on a gradual decrease of dosage.

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 doctor, pharmacist or other healthcare professional 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 allergic 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Dizziness, headache, drowsiness / sleepiness.
- Visual disturbances, including double vision.
- Flushing / red colouration of the skin.
- Muscle cramps.
- Increased blood sugar levels, causing blurry vision, frequent urination and fatigue.
- Depression, sleeplessness, mood changes (including anxiety), confusion.
- Increased tightness of muscle tone, tremor.
- Distortion of the sense of taste (taste perversion).
- Ringing or buzzing sound in the ears.
- 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).
- 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.

STORAGE AND DISPOSING OF CIPLAVASC:

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

PRESENTATION OF CIPLAVASC:

CIPLAVASC 5 and **CIPLAVASC 10** are both available in aluminium blister strips of 14 or 10 tablets packed in blister packs, each containing 28 or 30 tablets.

IDENTIFICATION OF CIPLAVASC:

CIPLAVASC 5: White, circular, flat, bevelled, uncoated tablet with '5' debossed on one face and central breakline on the other.

CIPLAVASC 10: White, circular, flat, bevelled, uncoated tablet with '10' debossed on one face and central breakline on the other.

REGISTRATION NUMBERS:

CIPLAVASC 5: A39/7.1/0117

CIPLAVASC 10: A39/7.1/0120

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Building 9, Parc du Cap, Mispel Street Bellville, 7530

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

First published: 11 February 2005

Reviewed: 15 February 2024