1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S3

MYLACAND PLUS (tablets)

Candesartan cilexetil 16 mg & Hydrochlorothiazide 12,5 mg

Contains sugar: Lactose 102,94 mg

Read all of this leaflet carefully before you start taking MYLACAND PLUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MYLACAND PLUS 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 MYLACAND PLUS is and what it is used for

What MYLACAND PLUS is:

MYLACAND PLUS is a combination of 2 active substances, candesartan cilexetil and hydrochlorothiazide:

- Candesartan is an angiotensin receptor blocker (ARB). It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This also helps to lower blood pressure.

What it is used for:

- MYLACAND PLUS is used to treat mild to moderate high blood pressure after you have been stabilised on the individual substances given at the same dosages.

2. What you need to know before you take MYLACAND PLUS:

Do not take MYLACAND PLUS:

- If you are hypersensitive (allergic) to candesartan cilexetil or hydrochlorothiazide, sulphonamide derivates (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of MYLACAND PLUS tablets;
- if you ever had a serious allergic reaction called “angioedema” when you have previously been treated with medicines called angiotensin-converting-enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). The signs including itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing. You must never again take these medicines.
- if you have severe heart disease;
- if you have various kidney diseases including disorders where the blood supply to your kidneys is reduced (renal artery stenosis);
- if you are receiving treatment with certain diuretics (water tablets) (see *Taking MYLACAND PLUS with other medicines*);
- if you have porphyria or gout;

- if you receive treatment with lithium (for mental health problems);
- if you are or want to become pregnant or breastfeeding (see *Pregnancy and breastfeeding and fertility)***;**
- Concomitant use of fluoroquinolones with ACE inhibitors/Renin-Angiotensin blockers is contraindicated in patients with moderate to severe renal impairment;
- if you have severe liver disease;
- if you have diabetes or kidney disease and are already taking a blood pressure-lowering medicine that contains aliskiren;
- if you have difficulty urinating or produce no urine;
- if you have narrowing of an artery or a heart valve;
- if you are taking a salt substitute that contains potassium, potassium supplements, or a potassium sparing diuretic (a specific kind of “water pill”);
- if you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Take special care with MYLACAND PLUS:

- If you have severe kidney disease, as regular monitoring must be done of certain laboratory tests (serum potassium and creatinine levels).
- If you take warfarin while taking MYLACAND PLUS, you may expect bleeding disorders.
- If you have abnormally low blood pressure (you feel like fainting, especially when you stand or sit up quickly).
- If you have had a kidney transplant your doctor will decide whether you may take MYLACAND PLUS.
- If you have heart failure, periodic evaluation will be done and should also include periodic monitoring of your kidney function. Changes may be made to your

MYLACAND PLUS treatment. Changes in function of the kidneys may be expected in some patients taking MYLACAND PLUS.

- If you have certain heart diseases, you must not take MYLACAND PLUS.
- If you have serious liver disease, your doctor will decide whether you may take MYLACAND PLUS.
- If you take MYLACAND PLUS with certain diuretics (water tablets), potassium supplements, salt substitutes containing potassium or other medicines that may increase potassium levels (e.g. heparin) it may lead to increases in serum potassium if you have high blood pressure.
- If you have heart failure and you are taking MYLACAND PLUS, you may have abnormally high concentration of potassium in your blood. Certain medicines can increase the amount of potassium in your blood such as water tablets. If you have certain serious heart diseases your doctor will decide whether you may take MYLACAND PLUS and he/she will monitor, you on a regular basis.
- If you are going to have an operation, tell your doctor or dentist if you are taking MYLACAND PLUS. This is because MYLACAND PLUS, when combined with some anaesthetics may cause a drop-in blood pressure. It may be so severe that you may have to receive specialised treatment.
- If you have severe heart disease or underlying kidney disease, treatment with medicines such as MYLACAND PLUS has been associated with acute low blood pressure, signs and symptoms of renal failure, passing less urine or acute kidney failure. If your blood pressure decreases too much and you have certain heart diseases, this could result in a heart attack or stroke.
- Concomitant use of fluoroquinolones and ACE inhibitors/rening-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients *(see Do not take MYLACAND PLUS*). Renal function should be assessed before initiating treatment,

and monitor during treatment, with fluoroquinolones or ACE inhibitors/renin-angiotensin receptor blockers.

- Have narrowing of an artery or a heart valve.
- Have diabetes.
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys.
- Are dehydrated or suffer from excessive vomiting, diarrhoea.
- A condition called primary hyperaldosteronism.
- If you have a family history of skin cancer.
- If you have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer) (see '*Risk of skin cancer'* below). Protect your skin from sun exposure and UV rays while taking MYLACAND PLUS.

Risk of skin cancer: MYLACAND PLUS contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking MYLACAND PLUS for many years (more than 3) or at a high dose.

While taking MYLACAND PLUS:

- Make sure to regularly check your skin for any new lesions.
- Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- Limit your exposure to the sun and to indoor tanning.

- Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
- Talk to your healthcare professional immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Sudden eye disorders: Treatment with hydrochlorothiazide in MYLACAND PLUS can cause sudden eye problems such as:

- Myopia: sudden near-sightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes. These eye disorders are related and can develop within hours to weeks of starting MYLACAND PLUS.

Children/ and adolescents

- Do not give MYLACAND PLUS to children as it is unlikely to be safe *(see How to take MYLACAND PLUS).*

Other medicines and MYLACAND PLUS

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

Tell your doctor if you are taking any of the following medicines:

- Lithium (a medicine used for mental health problems). Lithium concentrations may increase to toxic levels when taken with medicines such as MYLACAND PLUS.
- The effect of the treatment for high blood pressure may be increased when you take other high blood pressure medicines with MYLACAND PLUS.

- You could expect possible bleeding when MYLACAND PLUS is taken with warfarin.
- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury *(see section Do not take MYLACAND PLUS*).
- Other medicines to help lower your blood pressure, including betablockers, aliskiren-containing medicines, diazoxide andangiotensin converting enzyme (ACE) inhibitors such as enalapril, captopril, lisinopril or ramipril. If you are taking an ACE-inhibitor or aliskiren *(see 'Do not take MYLACAND PLUS' and 'Take special care with MYLACAND PLUS')*.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).

  Calcium or Vitamin D supplements.
- Medicines to lower your cholesterol, such as colestipol or cholestyramine.
- Medicines for diabetes (tablets or insulin).
- Medicines to control your heart beat (antiarrhythmic agents) such as digoxin.
- Medicines that can be affected by potassium blood levels such as some antipsychotic medicines.
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Laxatives.
- Penicillin or co-trimoxazole also known as trimethoprim/sulfamethoxazole (antibiotic medicines).
- Amphotericin (for the treatment of fungal infections).
- Lithium (a medicine for mental health problems).
- Steroids such as prednisolone.

- Medicines to treat cancer.
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Barbiturates (a type of sedative also used to treat epilepsy).
- Carbenoxolone (for treatment of oesophageal disease, or oral ulcers).
- Anticholinergic agents such as atropine and biperiden.
- Cyclosporine, a medicine used for organ transplant to avoid organ rejection.
- Other medicines that may lead to enhancement of the antihypertensive effect such as baclofen (a medicine for relief of spasticity), amifostin (used in cancer treatment) and some antipsychotic medicines.
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).

MYLACAND PLUS with food and drink and alcohol

- You may take MYLACAND PLUS with or without food or drinks.

Pregnancy and breastfeeding and fertility

- Safety in pregnancy and lactation has not been established *(see section Do not take MYLACAND PLUS)*.
- When pregnancy is planned or confirmed MYLACAND PLUS should be discontinued. Medicines affecting the renin-angiotensin system, such as MYLACAND PLUS, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women. Women of childbearing age should ensure effective contraception. Find out from your ~~doctor~~ healthcare professional what contraception will be most suitable for you.
- MYLACAND PLUS is excreted in breast milk and you should not breastfeed your baby while taking this medicine.

- If you become pregnant while you are taking MYLACAND PLUS, tell your doctor immediately so that he/she can give you a different medicine.

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

Driving and using machinery

MYLACAND PLUS may cause dizziness or weariness. It is not always possible to predict to what extent MYLACAND PLUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYLACAND PLUS affects them.

MYLACAND PLUS contains lactose

MYLACAND PLUS contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MYLACAND PLUS. If you have been told by your doctor that you have intolerance to some sugars, contact your ~~doctor~~ healthcare professional before taking MYLACAND PLUS.

3. How to take MYLACAND PLUS

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

Always take MYLACAND PLUS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- The recommended dose is one MYLACAND PLUS tablet once daily.
- The maximal antihypertensive effect is attained within 4 weeks of initiation of treatment.
- Try to take the tablet at the same time each day.

- This will help you to remember to take it.
- You should take MYLACAND PLUS with or without food.

Your doctor will tell you how long your treatment with MYLACAND PLUS will last.

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

If you take more MYLACAND PLUS than you should

- In the event of overdosage, consult your doctor or pharmacist.
- If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MYLACAND PLUS

- Do not take a double dose to make up for forgotten individual doses.
- Take the next dose as normal.

If you stop taking MYLACAND PLUS

- If you stop taking MYLACAND PLUS, your blood pressure may increase again. Therefore, do not stop taking MYLACAND PLUS without first talking to your doctor.

Use in children:

- Do not use MYLACAND PLUS in children.

If you have any further questions on the use of MYLACAND PLUS, ask your healthcare professional.

4. Possible side effects

MYLACAND PLUS can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching (with raised lumps);
- skin problems including rash caused by sensitivity to sunlight, severe rash that develops quickly with blistering or peeling of the skin and possibly blistering in the mouth, joint pain, fever, worsening of existing lupus erythematosus-like reactions or appearance of unusual skin reactions;
- fainting;
- sudden near sightedness or blurred vision (myopia);
- increased pressure in your eyes, eye pain, decrease in vision (glaucoma) ;
- build-up of liquid in your eye (choroidal effusion) with symptoms such as blind spots, eye pain, blurred vision;

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYLACAND PLUS. 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:

- Changes in how your liver is working, including inflammation of the liver (hepatitis) and jaundice. You may notice tiredness, yellowing of your skin and the whites of your eyes and flu-like symptoms;

- a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily;
- breathing difficulties (including lung inflammation and fluid in the lungs);
- inflammation of the pancreas. This causes abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Respiratory infection;
- hyperkalaemia (abnormally high concentration of potassium in the blood);
- light-headedness; feeling dizzy/spinning sensation (vertigo) and headache;
- low blood pressure - this may make you feel faint or dizzy.
- an increase in the amount of sugar (glucose) in your blood;
- an increase in the amount of uric acid in your blood;
- electrolyte imbalance (including deficiency of sodium in the blood and low potassium concentration in the blood);
- gout;
- low levels of chloride in the blood;
- sugar in your urine;
- weakness;
- raised or high levels of fats in your blood (including cholesterol).

The following side effects have been reported less frequently:

- Inflammation of the nasal passage; inflammation of a sinus;
- inflammation of the bronchial tubes;

- abnormal amounts of lipids and lipoproteins in the blood;
- dizziness;
- tachycardia;
- inflammation of the throat with dryness and pain;
- cough;
- abdominal (stomach) pain;
- nausea;
- back pain;
- influenza-like symptoms;
- urinary tract infection;
- injury;
- changes in blood test results: an increased amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, irregular heart beat or pins and needles;
- a reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps;
- pain in joints and muscles;
- effects on how your kidneys work, especially if you already have kidney disorders. Kidney failure may occur;
- sleep disturbance;
- depression;
- feeling restless;
- paraesthesia;
- problems with your sight for a short time;
- changes to your vision that can make things look yellow;
- feeling faint (especially when standing up);
- damage to blood vessels causing red or purple spots in the skin;
- anorexia; loss of appetite;

- gastric irritation;
- diarrhoea; constipation;
- skin problems including rash caused by sensitivity to sunlight;
- muscle spasm;
- increases in urea and serum creatinine.

The following side effects have been reported but the frequency is unknown:

- Cardiac dysrhythmias

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, pharmacist or nurse.

You can also report side effects to SAHPRA on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311.

By reporting side effects, you can help provide more information on the safety of MYLACAND PLUS.

5. How to store MYLACAND PLUS

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Keep the container tightly closed.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLACAND PLUS contains:

- The active substances are candesartan cilexetil and hydrochlorothiazide.
- The other ingredients are carmellose calcium, glycer[o]yl monostearate, hydroxypropyl cellulose, lactose monohydrate,magnesium stearate, maize starch, methylene chloride {colourants: iron oxide red, iron oxide yellow.

What MYLACAND PLUS looks like and contents of the pack:

Peach colour mottled, round, biconvex tablet debossed with “M” on one side and “CH2” on the other.

Cold form blisters are packed in pouches with a desiccant which is then inserted into a carton.

White HDPE securitainers containing a desiccant which is then inserted into a carton.

Holder of Certificate of Registration and Manufacturer

Mylan (Pty) Ltd

4 Brewery Street

Isando

1600

Republic of South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website