SCHEDULING STATUS

S3

MYLACAND 8 mg, tablets

Candesartan cilexetil, 8 mg

Contains sugar: Lactose 47,472 mg

MYLACAND 16 mg, tablets

Candesartan cilexetil, 14 mg

Contains sugar: Lactose 96,945 mg

Read this leaflet carefully before you start using MYLACAND.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MYLACAND 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 is and what it is used for.
2. What you need to know before you take MYLACAND.
3. How to take MYLACAND.
4. Possible side effects.
5. How to store MYLACAND.
6. Contents of the pack and other information.

1. What MYLACAND is and what it is used for

What MYLACAND is:

MYLACAND contains the active substance candesartan which belongs to a group of medicines known as angiotensin II receptor antagonists that lower blood pressure.

MYLACAND works by making your blood vessels relax and widen (which helps to lower your blood pressure). It also makes it easier for your heart to pump blood to all parts of your body.

What it is used for:

MYLACAND is used for:

- treating mild to moderate high blood pressure;
- treating heart failure.

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

Do not take MYLACAND:

- if you are hypersensitive (allergic) to [the active/s] or any of the other ingredients of MYLACAND;
- if you are hypersensitive (allergic) to candesartan cilexetil or any of the other ingredients of MYLACAND 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 include 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 MYLACAND;
- 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) such as spironolactone, triamterene or amiloride *(see 'MYLACAND and other medicines'*);
- if you have porphyria;
- if you receive treatment with lithium (for mental health problems). MYLACAND may increase the amount of lithium in your blood;
- if you are pregnant or breastfeeding *(see 'Pregnancy and breastfeeding and fertility'*);
- if you have severe liver diseases;
- if you have impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;

Concomitant use of fluoroquinolones with ACE inhibitors/Renin-Angiotensin blockers is contraindicated in patients with moderate to severe renal impairment.

Warnings and precautions

Take special care with MYLACAND:

Before you take, or whilst you are taking MYLACAND, tell your doctor:

- if you have any kidney disorders, as regular monitoring must be done of certain laboratory tests (serum potassium and creatinine levels);
- 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;
- if you have serious kidney disorders (*see 'Do not take MYLACAND'*) as you may experience changes in your kidney function;
- 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 treatment. Changes in function of the kidneys may be expected in some patients taking MYLACAND;
- if you have certain heart diseases, you must not take MYLACAND;
- if you have serious liver disease, your doctor will decide whether you may take MYLACAND;
- if you take MYLACAND with 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, you may have abnormally high concentration of potassium in your blood. Certain medicines can increase the amount of potassium in your blood e.g. such as water tablets called spironolactone, triamterene and amiloride *('see section Do not take MYLACAND'*). If you have certain serious heart diseases your doctor will decide whether you may take MYLACAND and he/she will monitor your potassium levels on a regular basis;
- if you are going to have an operation, tell your doctor or dentist if you are taking MYLACAND. This is because MYLACAND, 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 failure or underlying kidney disease. Treatment with medicines such as MYLACAND 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;
- if you have a condition of the adrenal gland called Crohn's disease (also called primary hyperaldosteronism);

Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients *('see section Do not take MYLACAND')*. Renal function should be assessed before initiating treatment, and monitored during treatment, with fluoroquinolones or ACE inhibitors/ renin-angiotensin receptor blockers.

- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE inhibitor (for example enalapril, lisinopril, ramipril, etc.), in particular if you have diabetes-related kidney problems.
  - aliskiren *('see section Do not take MYLACAND')*.

Children/ and adolescents

Do not give MYLACAND to children as it is unlikely to be safe.

Other medicines and MYLACAND

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 when taken with medicines such as MYLACAND.
- The effect of the treatment for high blood pressure may be increased when you take other high blood pressure medicines with MYLACAND, including ACE-inhibitors (such as enalapril, captopril, lisinopril or ramipril) or aliskiren *(see Do not take MYLACAND and Take special care with MYLACAND).*
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib, or etoricoxib (medicines used to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Warfarin (a medicine for thinning the blood). You could expect possible bleeding when MYLACAND is taken with warfarin.
- Diuretics (medicines known as 'water tablets') ('*see section Do not take MYLACAND'*).
- Candesartan, which is the active ingredient in MYLACAND, is not affected by food.

- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury *(see section 'Do not take MYLACAND')*.

MYLACAND with food and drink and alcohol

You may take MYLACAND with your food or drinks.

Pregnancy and breastfeeding and fertility

- Safety in pregnancy and breastfeeding has not been established.
- MYLACAND is excreted in breast milk and you should not breastfeed your baby while taking MYLACAND.
- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MYLACAND.
- If you become pregnant while you are taking MYLACAND, tell your doctor immediately so that he/she can give you a different medicine.
- MYLACAND is not recommended in pregnancy as it may cause serious harm to your baby.

Driving and using machinery

It is not always possible to predict to what extent MYLACAND 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 affects them.

MYLACAND contains lactose

MYLACAND 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. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking MYLACAND.

3. How to take MYLACAND

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

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

The usual dose is:

- It is important to keep taking MYLACAND every day.
- You should be taking MYLACAND with or without food.
- Try to take the tablet at the same time each day. This will help you to remember to take it.

High blood pressure:

- The usual dose of MYLACAND is 8 mg once a day.
- Your doctor may increase this dose to 16 mg once a day and further up to 32 mg once a day depending on blood pressure response.
- Some black patients may have a reduced response to this type of medicine, when given as the only treatment, and these patients may need a higher dose.

Heart failure:

- You will usually start to take 4 mg of MYLACAND once a day.
- Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32 mg once a day.
- MYLACAND can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.
- If you are an elderly patient no dose adjustment is necessary when you start or if you are a patient with kidney and mild to moderate liver disease.
- Your doctor may decide to give you MYLACAND alone or with other medicines for treatment of heart failure.

Use in children:

- Do not use MYLACAND in children.
- Your doctor will tell you how long your treatment with MYLACAND will last.
- If you have the impression that the effect of MYLACAND is too strong or too weak, tell your doctor or pharmacist.

If you take more MYLACAND 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

Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYLACAND

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

MYLACAND can have side effects.

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

If any of the following happens, stop taking MYLACAND 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, urticaria (smooth, slightly elevated area on the skin, which is redder and paler than the surrounding skin),or itching of skin;
- fainting.

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

- an increase in the number of infections you may get which causes fever, severe chills, sore throats, mouth ulcers or chesty coughs. These may be due to a low number of white blood cells;
- increased liver enzymes, abnormal liver function or inflammation of the liver. Abnormal liver function including inflammation of the liver (hepatitis) which may be seen as feeling sick (nausea), being sick (vomiting) loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin or whites of the eyes with pale stools or dark coloured urine. These may be signs of serious problems with your liver;
- kidney disease, including kidney failure. A decrease in kidney function which may be seen as producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain. These may be signs of serious kidney problems. In very rare cases kidney failure may occur.

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);
- dizziness/sensation of movement, headache;
- low blood pressure.

The following side effects have been reported less frequently:

- blood tests showing changes in the number of red blood cells, white blood cells or platelets;
- hyponatraemia (salt depletion);
- nausea;
- back pain, pain in joints and muscles;
- cough.

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

- diarrhoea

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

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

5. How to store MYLACAND

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place.

Store in the original package / container.

Keep the container well closed.

Protect from light / moisture.
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 contains:

The active substance is:
MYLACAND 8 mg tablets: Candesartan cilexetil 8 mg
MYLACAND 16 mg tablets: Candesartan cilexetil 16 mg

The other ingredients are carmellose calcium, glyceryl monostearate, hydroxypropyl cellulose, iron oxide red, maize starch, magnesium stearate

What MYLACAND looks like and contents of the pack:

What MYLACAND looks like:

MYLACAND 8 mg:

Pink mottled, capsule shaped, biconvex tablet debossed with “M” and “8” on either side of the break line on one side and plain on the other side.

MYLACAND 16 mg:

Pink mottled, capsule shaped, biconvex tablet debossed with “M” and “16” on either side of the break line on one side and plain on the other side.

Contents of the pack:

MYLACAND 8 mg and 16 mg:

Cold form blister pack comprises of cold form laminate (aluminium foil laminated to oriented polyamide on one side and to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil on the other side. Blister packs are packed in triple laminated pouch with desiccant between the blister pack and triple laminated pouch and sealed. Pouch is placed in a carton.

HDPE bottle pack comprises of a white opaque HDPE bottle with a white opaque screw cap with induction sealing liner with absorbent cotton and desiccant in 30’s and 90’s. The HDPE bottle is placed in a carton.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd
4 Brewery Street, Isando
Johannesburg,
1609

This leaflet was last revised in

Date of publication: 04 June 2013
Date of revision of text: 19 December 2023

Registration number

MYLACAND 8 mg: 45/7.1.3/0301
MYLACAND 16 mg: 45/7.1.3/0302

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website