PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

BIO CAPTOPRIL 12,5 mg, tablets

BIO CAPTOPRIL 25 mg, tablets

Captopril

Contains sugar (lactose anhydrous) BIO CAPTOPRIL 12,5 mg contains 26 mg per tablet and

BIO CAPTOPRIL 25 mg contains 52 mg per tablet.

Read all of this leaflet carefully before you start taking BIO CAPTOPRIL

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

1. What BIO CAPTOPRIL is and what it is used for

Captopril is a member of a group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors. ACE inhibitors reduce constriction of blood vessels, which makes it easier for the blood to flow through them.

– BIO CAPTOPRIL is used to lower high blood pressure and/ or to help treat people with heart failure.

2. What you need to know before you take BIO CAPTOPRIL

Do not take BIO CAPTOPRIL:

- if you are hypersensitive (allergic) to captopril or any of the other ingredients of BIO CAPTOPRIL (listed in section 6)
- if you are you pregnant or planning to become pregnant
- if you are you breastfeeding
- if you have or you ever had a reaction that included swelling of the hands, face, lips or tongue, caused by medicines or where the cause was unknown
- if you have or you inherited a condition from your parents that involves swelling of the hands, face, lips or tongue
- if you have a narrowing of your aortic valve
- if you have a heart condition where your heart is enlarged
- if you have impaired kidney function or a narrowing in the kidney tubes (one or both kidneys)
- if you are taking diuretics (water pills) such as amiloride, spironolactone, triamterene
- if you have porphyria
- if you have Addison's disease (long-term endocrine disorder)
- if you are taking lithium
- if you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are treated with a blood pressure lowering medicine containing sacubutril/ valsartan.

Warnings and precautions

Take special care with BIO CAPTOPRIL:

- **You must tell your doctor if you think you are (or might become) pregnant.**

BIO CAPTOPRIL tablets should not be taken if you are pregnant (see section Pregnancy and breastfeeding).

- If you get swelling in your face, neck or throat.
- If you are being treated with sacubutril/ valsartan, you should not take BIO CAPTOPRIL.
- If you are black, you are at higher risk of developing angioedema than in non-black patients.
- If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased: sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs).
- If you suffer from kidney disease.
- If you are receiving immune-suppressant therapy.
- If you suffer from any collagen vascular diseases such as rheumatoid arthritis, systemic lupus erythematosus or scleroderma.
- If you experience more infections such as sore throat of fever which can be due to changes in your blood cells and can be monitored by blood test carried out by your doctor.
- If you are having dialysis with high flux membranes e.g., AN69.
- If you are about to have treatment for the removal of cholesterol from your blood by a machine (called LDL apheresis).
- If you are going to have desensitisation treatment, e.g., for an allergic reaction to wasp or bee stings.
- Your doctor may check your kidney function, blood pressure, and the number of electrolytes (e.g., potassium) in your blood at regular intervals (see “do not take BIO CAPTOPRIL”).
- If you are undergoing dialysis. There have been some reports of allergic-type reactions seen when people using medicine such as BIO CAPTOPRIL undergo dialysis. Tell your doctor before your next dialysis treatment.
- If you have recently suffered from excessive diarrhoea or vomiting.
- If you suffer from low blood pressure (hypotension).
- If you are taking diuretic medicines (water tablets).

- If you are taking potassium-sparing diuretics (e.g., triamterene, amiloride and spironolactone), potassium-containing supplements or salt substitutes or medicines which can increase the level of potassium in the blood e.g., heparin, co-trimoxazole (see "Other medicines and BIO CAPTOPRIL").
- If you feel ill, become aware of your heartbeat and get muscle weakness - you may have high amounts of potassium in your blood, your doctor will perform a blood test to check this.
- If you are currently suffering from a cough.
- If you are going to have dental surgery or major surgery involving anaesthetic, you should make sure that the anaesthetist is aware you are taking BIO CAPTOPRIL.
- If you get any changes in the colour of your skin or the whites of your eyes, you must see your doctor immediately.
- If you suffer from liver disease.
- If your kidneys are not working properly.
- If you suffer from porphyria, you should not take BIO CAPTOPRIL.
- If you have suffered from heart disease, especially narrowing of the heart valves, restricting the blood flow (aortic stenosis or mitral stenosis) or thickening of the heart muscle (hypertrophic cardiomyopathy), you should not take BIO CAPTOPRIL.
- Tell your doctor if you are taking BIO CAPTOPRIL tablets before you have any blood or urine tests as BIO CAPTOPRIL tablets may interfere with the results of some tests.
- If you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans – for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren.
- If you are taking lithium, a medicine used to treat mood disorders [antipsychotic] (see "Other medicines and Captopril").

- If you have diabetes. In rare cases BIO CAPTOPRIL has been found to increase the blood sugar lowering effects of antidiabetic medicines. This may happen in the first few weeks of treatment. If this happens you should contact your doctor who may decide to adjust the dose of your antidiabetic medicine.

Other medicines and BIO CAPTOPRIL

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

It is especially important to tell your doctor if you are taking any of the following:

- Medicines from pharmacies for colds, coughs, hay fever or sinus problems as these may increase your blood pressure.
- Diuretics (water tablets).
- Potassium supplements or salt substitutes containing potassium (e.g., triamterene, amiloride and spironolactone).
- Non-steroidal anti-inflammatory painkiller (NSAIDs) (e.g., indomethacin and ibuprofen).
- Medicines to treat mental problems including manic depression or depression (e.g., lithium and amitriptyline).
- Medicines to treat high blood pressure (e.g., beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine and nifedipine).
- Any medicine that may be used during and after a heart attack.
- Medicines that cause dilation of the blood vessels (e.g., minoxidil, and clonidine).
- Medicines to treat gout (e.g., allopurinol and probenecid).
- Immuno-suppressants (e.g., azathioprine and cyclophosphamide).
- Medicines to treat irregular heartbeats (e.g., procainamide).
- Medicines to treat diabetes (e.g., oral antidiabetics and insulin).
- BIO CAPTOPRIL may cause a false-positive urine test for acetone.

- Medicines to treat high blood pressure (e.g., aliskiren), see section "Do not take BIO CAPTOPRIL".
- Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".
- Medicines to treat diabetes (e.g., vildagliptin).
- Medicines used to treat heart failure (e.g., sacubutril/ valsartan). See section "Do not take BIO CAPTOPRIL".
- Injectable gold preparations (e.g., sodium aurothiomalate).

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BIO CAPTOPRIL with food and drink

Moderate amounts of alcohol will not affect BIO CAPTOPRIL. However, you should check with your doctor whether drinking is advisable for you. BIO CAPTOPRIL should be taken one hour before food intake.

Pregnancy and breastfeeding

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 healthcare provider for advice before taking BIO CAPTOPRIL.
It is not safe to use BIO CAPTOPRIL during pregnancy or breastfeeding. You should notify your doctor if you become or intend to become pregnant while on BIO CAPTOPRIL treatment.

Driving and using machines

BIO CAPTOPRIL can affect your ability to drive, usually when you first start taking your medicine or if your doctor changes your dose. However, if you feel light-headed, dizzy, drowsy or you have disturbed vision you should not drive or use machinery while taking BIO CAPTOPRIL (see section 4 "Possible side effects").

It is not always possible to predict to what extent BIO CAPTOPRIL may interfere with your daily activities. You should ensure that you do not engage in driving or using machines until you are aware of the measure to which BIO CAPTOPRIL affects you.

BIO CAPTOPRIL contains lactose

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

3. How to take BIO CAPTOPRIL

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

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

Do not take more or less tablets and do not take them more often than recommended.

For the treatment of high blood pressure (hypertension)

The usual starting dose for the treatment of high blood pressure is 25 mg two or three times a day. Your doctor may gradually increase this dose to 100 – 150 mg a day. You may also need to be given other medicines to lower your blood pressure.

Older patients and those with kidney problems may be given a lower starting dose.

In heart failure

The usual starting dose in heart failure is 6,25 mg or 12,5 mg three times a day which will then be increased by your doctor to a maximum of 300 mg a day.

Your doctor will tell you how long your treatment with BIO CAPTOPRIL will last. If you have the impression that the effect of BIO CAPTOPRIL is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO CAPTOPRIL than you should

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

If you are going to the hospital, take the empty container and any remaining tablets with you. If the person has fainted, lay them down and raise their feet higher than their head.

If you forget to take BIO CAPTOPRIL

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

Effects when treatment with BIO CAPTOPRIL is stopped

Do not stop taking this medicine without telling your doctor first because it will affect your blood pressure.

4. Possible side effects

BIO CAPTOPRIL can have side effects.

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

If any of the following happens, stop taking BIO CAPTOPRIL 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
- fainting or unusually fast and or irregular heartbeat
- yellowing of the skin and eyes, also called jaundice
- anaphylactoid reactions.

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

Less frequent side effects:

- sore throat or fever,
- severe abdominal pain,
- a sudden, unexplained, rash or burning, red or peeling skin,
- chest pain (angina),
- less urine than is normal for you,
- more urine than is normal for you.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- loss of appetite and weight loss,
- sleep disorders,
- difficulty sleeping,
- dizziness,
- high levels of potassium in the blood, low levels of sugar in the blood,
- confusion, depression,
- changes in or loss of taste (dysgeusia),
- reversible and self-limiting taste impairment,
- low blood pressure (you may experience dizziness, fainting or light headedness,
- dry irritating cough and dyspnoea (difficulty in breathing),
- nausea,

- vomiting,
- gastric irritation and abdominal pain,
- diarrhoea or constipation,
- dry mouth,
- rash with or without itching,
- hair loss.

Less frequent side effects:

- blood disorders, including anaemia, thrombocytopenia, neutropenia, agranulocytosis and pancytopenia (weakness, poorer than normal blood clotting and bruising very easily or make infections more likely),
- eosinophilia (frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells,
- swollen glands,
- auto-immune diseases,
- positive Anti-Nuclear Antibody test (ANA), used to detect auto-immune disorders,
- serum sickness like syndrome,
- anorexia,
- abnormally low levels of salt (sodium) in blood (hyponatremia),
- drowsiness,
- pins and needles,
- headache,
- mini stroke,
- problems with the blood vessels in the brain including stroke and fainting (syncope),
- blurred vision,
- disturbed vision, dry and or itching eyes,

- skipping or fluttering heartbeat, faster heartbeat,
- heart problems including heart attack,
- heart suddenly and unexpectedly stops beating (cardiac arrest) or weakened heart (cardiogenic shock)
- reduced blood flow to the hands and feet (e.g., Raynaud syndrome),
- flushing,
- pale skin,
- low blood pressure after a change in position i.e. when standing up from a lying or sitting position (orthostatic hypotension),
- difficulty in breathing,
- runny nose,
- allergic lung inflammation or lung infection,
- sore mouth and mouth ulcers,
- stomach ulcers,
- swelling of the intestines which may cause stomach pain, with or without being sick (intestinal angioedema),
- burning sensation of the oral mucosa in the absence of specific oral lesion,
- inflammation of the pancreas,
- inflammation of the tongue,
- impaired liver function and raised liver enzymes,
- swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema), particularly the arms and legs, face, lips, respiratory, digestive, and urinary tracts, tongue, throat, voice box,
- Stevens-Johnson syndrome (a serious illness with blistering of the skin mouth, eyes and genitals),
- skin disorders (blistering, peeling),
- peeling of the skin over large areas of the body (erythroderma, exfoliative dermatitis),
- sensitivity of the skin to light,
- pains in the muscles and joints,

- protein in the urine (nephrotic syndrome, proteinuria),
- increased urgency to urinate
- chronic disease of the kidney which can lead to blood or protein in the urine
- impotence,
- swelling of the breasts,
- loss of sexual drive
- fatigue,
- cold extremities,
- feeling generally unwell,
- general weakness (asthenia),
- increase of creatinine in the blood,
- increase of potassium or bilirubin in the blood,
- decrease of haemoglobin, haematocrit, leucocytes and thrombocytes (blood cells and platelets),
- increase in ESR (a blood test to measure inflammation in the body).

Frequency unknown of following side effects:

- poor muscle control that causes clumsy voluntary movements,
- nervousness, sleepiness,
- a syndrome which may include fever, joint stiffness/ pain, facial, kidney disorder, inflammation of the blood vessels, rash and skin disorders, high level of disease-fighting white blood cells and inflammation marker in your blood,
- a weakness and rapid fatigue of muscles under voluntary control.

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction 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 BIO CAPTOPRIL.

5. How to store BIO CAPTOPRIL

- Store all medicines out of reach of children.
- Store at or below 25 °C, in a dry place.
- Keep the tablets in the original container until required for use.
- Protect from light and moisture.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What BIO CAPTOPRIL contains:

The active substance is captopril. The tablets come in the following different strengths: 12,5 mg and 25 mg.

The other ingredients are colloidal silicon dioxide, lactose anhydrous, microcrystalline cellulose, palmitic acid, starch and talc.

What BIO CAPTOPRIL looks like and contents of the pack

BIO CAPTOPRIL 12,5 mg: A white to off-white, round, flat, bevelled edged tablet with a break line debossed on one side and plain on the other side.

BIO CAPTOPRIL 25 mg: A white to off-white, round, flat, bevelled edged tablet with a break line debossed on one side and plain on the other side.

BIO CAPTOPRIL 12,5 mg is packed in securitainers with 100 tablets.

BIO CAPTOPRIL 25 mg is packed in securitainers with 60 tablets.

Holder of Certificate of Registration

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