

BIO CAPTOPRIL

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 26,0 mg per tablet and BIO CAPTOPRIL 25 mg contains 52,0 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

- What BIO CAPTOPRIL is and what it is used for
- What you need to know before you take BIO CAPTOPRIL
- How to take BIO CAPTOPRIL
- Possible side effects
- How to store BIO CAPTOPRIL
- 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 (waterpills) 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 amount 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 you 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 spirono-lactone), 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).

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 CAPTO-PRIL 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 (bistering, 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: White to off-white, round, flat, bevelled edged tablet, with breakline debossed on one side, plain on the other.

BIO CAPTOPRIL 25 mg: White to off-white coloured, round, flat bevelled edges uncoated tablets, plain on one side and cross-line marking on other side, free from cracks, mottling and chips in the tablet surface.

BIO CAPTOPRIL 12,5 mg and BIO CAPTOPRIL 25 mg is packed in white HDPE containers as 60 tablets.

Holder of Certificate of Registration

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BIO CAPTOPRIL 25 mg: 31/7.1/0658

Botswana	
Reg. No. BOT0600858	S2

BIO CAPTOPRIL

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

[S3]

BIO CAPTOPRIL 12,5 mg, tablette

BIO CAPTOPRIL 25 mg, tablette

Kaptopril

Bevat suiker (watervrye laktose)
BIO CAPTOPRIL 12,5 mg bevat 26,0 mg per tablet en BIO CAPTOPRIL 25 mg bevat 52,0 mg per tablet.

Lees die hele pamflet noukeurig deur voordat jy begin om BIO CAPTOPRIL te neem

- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
 - Indien jy verdere vrae het vra asseblief vir jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
 - BIO CAPTOPRIL is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag hulle skade aandoen, al is hul simptome dieselfde as joune.
- Wat is in hierdie pamflet**
- Wat BIO CAPTOPRIL is en waarvoor dit gebruik word
 - Wat jy moet weet voordat jy BIO CAPTOPRIL neem
 - Hoe om BIO CAPTOPRIL te neem
 - Moontlike nuwe-effekte
 - Hoe om BIO CAPTOPRIL te bewaar
 - Inhoud van die pak en ander inligting

1. Wat BIO CAPTOPRIL is en waarvoor dit gebruik word

Kaptopril is ’n lid van ’n groep medisyne wat Angiotensienomskakelende ensiem (ACE) Inhibeerders genoem word. ACE inhibeerders verlaag die vernouing van bloedvate wat dit makliker maak vir die bloed om deur hulle te vloei.

– BIO CAPTOPRIL word gebruik om hoë bloeddruk te verlaag en/ of mense met hartversaking te help behandel.

2. Wat jy moet weet voordat jy BIO CAPTOPRIL neem

Moenie BIO CAPTOPRIL neem nie:

- Indien jy hipersensitief (allergies) is vir kaptopril of vir enige van die ander bestanddele van BIO CAPTOPRIL (gelys in afdeling 6)
- Indien jy swanger is of beplan om swanger te raak
- Indien jy borsvoed
- Indien jy ’n reaksie het, of al gehad het, wat swelling van die hande, gesig, lippe of tong insluit wat veroorsaak word deur medisyne of waar die oorsaak onbekend was
- indien jy ’n toestand geërf van jou ouers wat swelling van die hande, gesig, lippe of tong veroorsaak
- indien jy ’n vernouing van jou aortaklep het
- indien jy ’n harttoestand het waar jou hart vergroot is
- indien jy verswakte nierfunksie het of ’n vernouing in die nierbuis (een of albei niere)
- indien jy diuretika (waterpille) neem soos amiloried, spironolaktoon, triamtereen
- indien jy proferiee het
- indien jy Addison se siekte het (langtermyn endokriene versteuring)
- indien jy litium neem
- indien jy behandel word met ’n bloeddrukverlagende medisyne wat aliskirien bevat.
- indien jy behandel word met ’n bloeddrukverlagende medisyne wat sakubutriel/ valsartan bevat.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met BIO CAPTOPRIL:

- jy moet jou dokter vertel indien jy dink dat jy swanger is (of swanger mag raak). BIO CAPTOPRIL tablette moet nie geneem word as jy swanger is nie (sien afdeling Swangerskap en borsvoeding).
- Indien jy swelling in jou gesig, nek of keel kry.
- Indien jy behandel word met sakubutriel/ valsartan, moet jy nie BIO CAPTOPRIL neem nie.
- Indien jy swart is, loop jy ’n groter risiko om angioedeem te ontwikkel as by nie-swart pasiënte.
- Indien jy enige van die volgende medisyne neem word die risiko vir angioedeem (skielike swelling onder die vel in areas soos die keel) verhoog: sirolimus, everolimus en ander medisyne wat aan die klas van mTOR inhibeerders behoort (gebruik om verwerping van oorgeplante organe te verhoed).
- Indien jy aan niersiekte ly.
- Indien jy immuunonderdrukkende terapie ontvang.
- Indien jy aan enige kollagene vasculêre siektes ly soos rumatoïede artritis, sistemiese lupus erythematosus of sklerodermie.
- Indien jy meer infeksies ervaar soos ’n seer keel of koors wat kan voorkom as gevolg van veranderinge in jou bloedselle. Dit kan gemonitor word deur bloedtoetse deur jou dokter.
- Indien jy dialise ontvang met hoë vloed membrane, bv. AN69.
- Indien jy op die punt staan om behandeling te kry vir die verwydering van cholesterol uit jou bloed deur ’n masjien (genoem LDL-aferese).
- Indien jy desensitiseringsbehandeling gaan kry, bv. vir ’n allergiese reaksie op perdeby- of bysteke.
- Jou dokter mag jou nierfunksie, bloeddruk en die hoeveelheid elektroliete (bv. kalium) in jou bloed met gereelde tussenposes nagaan (sien “moenie BIO CAPTOPRIL neem nie”).
- Indien jy dialise ontvang. Daar is ’n paar verslae van allergiese-tipe reaksies gesien wanneer mense wat medisyne soos BIO CAPTOPRIL gebruik dialise ondergaan.

Vertel jou dokter voor jou volgende dialisebehandeling.

- Indien jy onlangs aan oormatige diarree of braking gely het.
- Indien jy aan lae bloeddruk ly (hipotensie).
- Indien jy diuretika medisyne neem (watertablette).
- Indien jy kaliumbesparende diuretika (bv. triamtereen, amiloried en spironolaktoon), kaliumbevattende aanvullings of soutvervangers of medisyne neem wat die vlak van kalium in die bloed kan verhoog, bv. heparien, ko-trimoksasool (sien “Ander medisyne en BIO CAPTOPRIL”).
- Indien jy siek voel, bewus word van jou hartklop en spierswakheid kry – jy mag dalk hoë hoeveelhede kalium in jou bloed hê. Jou dokter sal ’n bloedtoets doen om dit na te gaan.
- Indien jy tans aan ’n hoës ly.
- Indien jy tandheelkundige chirurgie of ’n groot operasie gaan ondergaan wat narkose behels, moet jy seker maak dat die narkotiseur bewus is dat jy BIO CAPTOPRIL neem.
- Indien jy enige veranderinge in die kleur van jou vel of die wit van jou oë kry, moet jy dadelik jou dokter sien.
- Indien jy aan lewersiekte ly.
- Indien jou niere nie ordentlik werk nie.
- Indien jy aan porfirie ly moet jy nie BIO CAPTOPRIL neem nie.
- Indien jy aan hartsiektes gely het, veral vernouing van die hartkleppe, beperking van die bloedsvloei (aortastenose of mitrale stenose) of verdikking van die hartspier (hipertrofiese kardiomiopatie), moet jy nie BIO CAPTOPRIL neem nie.
- Vertel jou dokter indien jy BIO CAPTOPRIL tablette neem voordat jy enige bloed- of urienetoetse doen, aangesien BIO CAPTOPRIL tablette mag inmeng met die resultate van sommige toetse.
- Indien jy enige van die volgende medisyne neem vir hoë bloeddruk:
 - ’n angiotensien II reseptorblokker (ARBs) (ook bekend as sartans – byvoorbeeld valsartan, telmisartan, irbesartan), veral as indien jy diabetes-verwante nierprobleme het.
 - aliskirien.
- Indien jy litium neem, ’n medisyne wat gebruik word om gemoedsversteurings te behandel (antipsigotikum) (sien ’ander medisyne en BIO CAPTOPRIL”).
- Indien jy diabetes het. In skaars gevalle is dit gevind dat BIO CAPTOPRIL die bloedsuikerverlagende effekte van antidiabetiese medisyne verhoog. Dit mag gebeur gedurende die eerste paar weke van behandeling. Indien dit gebeur, moet jy jou dokter kontak wie mag besluit om jou dosis van die antidiabetiese medisyne aan te pas.

Ander medisyne en BIO CAPTOPRIL

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Dit is veral belangrik om jou dokter te vertel indien jy enige van die volgende neem:

- Medisyne van apteke vir verkoue, hoës, hooikoors of sinusprobleme, aangesien hierdie medisyne jou bloeddruk mag verhoog.
- Diuretika (watertablette).
- Kaliumaanvullings of soutvervangers wat kalium bevat (bv. triamtereen, amiloried en spironolaktoon).
- Nie-steroidale anti-inflammatoriese pynstillers (NSAIDs) (bv. indometasien en ibuprofeen).
- Medisyne om geestelike probleme te behandel, insluitend maniese depressie (bv. litium en amitriptilien).
- Medisyne om hoë bloeddruk te behandel (bv. beta-blokkers soos propranolol, atenolol of kalsiumkanaalblokkers soos amlodipien en nifedipien).
- Enige medisyne wat gebruik mag word gedurende en na ’n hartaanval.
- Medisyne wat dilatasie van die bloedvate kan veroorsaak (bv. minoksidil en klonidien).
- Medisyne om jig te behandel (bv. allopurinol en probenesid).
- Immuunonderdrukkers (bv. asatioprien en siklofosfamid).
- Medisyne om ongereelde hartklop te behandel (bv. prokainamied).
- Medisyne om diabetes te behandel (bv. orale anti-diabetiese medisyne en insulien).
- BIO CAPTOPRIL mag ’n fals-positiese oriëntoets veroorsaak vir asetoon.
- Medisyne om hoë bloeddruk te behandel (bv. aliskirien), sien afdeling “Moenie BIO CAPTOPRIL neem nie”.
- Medisyne wat gereeld gebruik word om verwerping van oorgeplante organe te verhoed (sirolimus, everolimus en ander medisyne wat aan die klas van mTOR inhibeerders behoort). Sien afdeling “waarskuwings en voorsorgmaatreëls”.
- Medisyne om diabetes te behandel (bv. vildaglijen).
- Medisyne gebruik om hartversaking te behandel (bv. sakubutriel/ valsartan). Sien afdeling “Moenie BIO CAPTOPRIL neem nie”.
- Insuitbare goudpreparate (bv. natriumauriotimalaai).

BIO CAPTOPRIL met kos en drank

Matige hoeveelhede alkohol sal nie BIO CAPTOPRIL affekteer nie. Jy moet egter seker maak by jou dokter of alkoholiname raadsaam is vir jou. BIO CAPTOPRIL moet een uur voor voedsel inname geneem word.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om ’n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO CAPTOPRIL neem. Dit is nie veilig om BIO CAPTOPRIL gedurende swangerskap en borsvoeding te gebruik nie. Jy moet jou dokter in kennis stel indien jy swanger raak of beplan om swanger te raak terwyl jy op BIO CAPTOPRIL-behandeling is.

Bestuur en die gebruik van masjiene

BIO CAPTOPRIL kan jou vermoë om te bestuur affekteer, gewoonlik wanneer jy begin om jou medisyne te neem of wanneer die dokter jou dosis aanpas. Indien jy egter lighoofdig, duiselig of lomerig voel of indien jy versteurde visie het, moet jy nie bestuur of masjinerie gebruik terwyl jy BIO CAPTOPRIL neem nie (sien afdeling 4 “Moontlike nuwe-effekte”).

Dit is nie altyd moontlik om te voorspel tot watter mate BIO CAPTOPRIL mag inmeng met jou daaglike aktiwiteite nie. Jy moet verseker dat jy nie betrokke raak by bestuur of die gebruik van masjiene totdat jy bewus is van die mate waartoe BIO CAPTOPRIL jou affekteer nie.

BIO CAPTOPRIL bevat laktose

Indien jy deur jou dokter vertel is dat jy ’n onverdraagsaamheid het vir sekere suikers, kontak jou dokter voordat jy BIO CAPTOPRIL neem.

3. Hoe om BIO CAPTOPRIL te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd BIO CAPTOPRIL presies soos jou dokter of apteker vir jou vertel het. Maak seker by jou dokter of apteker indien jy nie seker is nie. Moenie meer of minder tablette neem nie en moet hulle nie meer gereeld neem as wat aanbeveel is nie.

Vir die behandeling van hoë bloeddruk (hipertensie)

Die gewone aanvangsdosis vir die behandeling van hoë bloeddruk is 25 mg twee of drie keer per dag. Jou dokter mag hierdie dosis geleidelik verhoog tot 100 – 150 mg ’n dag. Jy mag ook ander medisyne gegee word om jou bloeddruk te verlaag. Ouer pasiënte en die met nierprobleme mag ’n laer aanvangsdosis gegee word.

In hartversaking

Die gewone aanvangsdosis in hartversaking is 6,25 mg of 12,5 mg drie keer per dag wat dan deur jou dokter verhoog sal word tot ’n maksimum van 300 mg ’n dag.

Jou dokter sal jou vertel hoe lank jou behandeling met BIO CAPTOPRIL sal aanhou. Indien jy die indruk het dat die effek van BIO CAPTOPRIL te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer BIO CAPTOPRIL neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie kontak die naaste hospitaal of gifsentrum. Indien jy na die hospitaal gaan, neem die leë houer en die oorblywende tablette saam met jou. Indien die persoon flou geword het, lê hulle neer en lig hulle voete hoër as hulle kop.

Indien jy vergeet om BIO CAPTOPRIL te neem

Indien jy vergeet om ’n dosis te neem, neem dit sodra jy daarvan onthou. Moenie ’n dubbele dosis neem om op te maak vir die vergete individuele dosisse nie. Gaan voort en neem jou volgende tablet op die gewone tyd.

Effekte wanneer behandeling met BIO CAPTOPRIL gestaak word

Moenie ophou om hierdie medisyne te neem sonder om eers jou dokter te vertel nie, aangesien dit jou bloeddruk sal affekteer.

4. Moontlike nuwe-effekte

BIO CAPTOPRIL kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir BIO CAPTOPRIL aangemeld is word in hierdie pamflet beskryf nie. Indien jou algemene gesondheid sou versleg of indien jy enige ongewens-de effekte ervaar terwyl jy BIO CAPTOPRIL neem, raadpleeg asseblief jou gesondheid-sorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BIO CAPTOPRIL te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeilike sluk en asemhaling kan veroorsaak
 - veluitslag of jeuk
 - floute of buitengewone vinnige en/ of onreëlmatige hartklop
 - vergeling van die vel en oë, genaamd geelsug
 - anafalktoïede reaksies.
- Hierdie is almal baie ernstige nuwe-effekte. Indien jy hulle het mag jy dalk ’n ernstige reaksie vir BIO CAPTOPRIL gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddelik vir jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy die volgende opmerk:

Minder gereelde nuwe-effekte:

- seer keel of koors,
 - erge maagpyn,
 - ’n skielike, onverklaarbare veluitslag of brandende gevoel, rooi of afskilferende vel,
 - borspyn (angina),
 - minder uriene as wat normaal is vir jou,
 - meer uriene as wat normaal is vir jou.
- Hierdie is almal ernstige nuwe-effekte. Jy mag dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- verlies van aptyt en gewigsverlies,
- slaapversteurings,
- moeilike slaap,
- duiseligheid,
- hoë vlakke van kalium in die bloed, lae vlakke van suiker in die bloed,
- verwarring, depressie,
- veranderinge in of verlies van smaak (disgeusie),
- omkeerbare en selfbeperkende smaakinkorting,
- lae bloeddruk (jy mag duiseligheid, floute of lighoofdigheid ervaar),

- droë, irriterende hoës en dispnee (moeilike asemhaling),
- naarheid,
- braking,
- maagirritasie en maagpyn,
- diarree of hardlywigheid,
- droë mond,
- veluitslag met of sonder jeuk,
- haarverlies.

Minder gereelde nuwe-effekte:

- bloedafwykings, insluitend bloedarmoede (anemie), trombositopenie, neutropenie, agranulositose en pansitopenie (swakheid, stadiger as normale bloedstolling en baie maklik kneusing of maak infeksies meer waarskynlik),
- eosinofilie (gereelde hyg, asemnood, buikpyn, diarree, koors, hoës en uitslag as gevolg van ’n toename in sekere witbloedselle),
- geswelde kliere,
- outo-immuun siektes,
- positiewe Anti-nukleêre teenliggaampiestoets (ANA), wat gebruik word om outo-immuunafwykings op te spoor,
- serumsiekte-agtige sindroom,
- anoreksie,
- abnormale lae vlakke van sout (natrium) in bloed (hiponatremie),
- lomerigheid,
- naalde en spelde,
- hoofpyn,
- mini beroerte,
- probleme met die bloedvate in die brein insluitend beroerte en floute (sinkopie),
- versteurde visie,
- versteurde visie, droë en jeukende oë,
- hartklop wat slae oorslaan of fladderende hartklop, vinniger hartklop,
- hartprobleme insluitende hartaanval,
- hartklop stop skielik on onverwags (hartstilstand) of verswakte hart (kardiogene skok),
- verlaagde bloedsvloei na die hande en voete (bv. Raynaud se sindroom),
- blosing,
- bleek vel,
- lae bloeddruk na ’n verandering in posisie, d.w.s wanneer jy opstaan vanuit ’n ligging of sittende posisie (ortostatiese hipotensie),
- moeilike asemhaling,
- loopneus,
- allergiese longinflammasie of longinfeksie,
- seer mond en mondseer,
- maagsere,
- swelling van die ingewande wat maagpyn kan veroorsaak, met of sonder om siek te wees (derm-angioedeem),
- brandende sensasie van die mondslymvliese in die afwesigheid van spesifieke mondletsel,
- inflammasie van die pankreas,
- inflammasie van die tong,
- verswakte leverfuksie en verhoogde lewerensieme,
- swelling van die dieper lae van die vel wat veroorsaak word deur ’n opbou van vloeistof (angioedeem), veral die arms en bene, gesig, lippe, respiratoriese, spysverterings en urienweë, tong, keel, stemkas,
- Stevens Johnson se sindroom (’n ernstige siekte met blasies van die vel, mond, oë en geslagsdele),
- Velversteurings (blasies, afskilfering),
- afskilfering van die vel oor groot areas van die liggaam (eritroderma, eksfoliatiewe dermatitis),
- sensitiwiteit van die vel vir lig,
- pyne in die spiere en gewigte,
- proteïen in die uriene (nefrotiese sindroom, proteïenurie),
- verhoogde dringendheid om te urineer
- chroniese niersiekte wat kan lei tot bloed of proteïene in die uriene,
- impotensie,
- swelling van die borste,
- verlies van seksdrang,
- moegheid,
- koue ledemate,
- algemene ongestelde gevoel,
- algemene swakheid (astenie),
- verhoogde kreatinien in die bloed,
- verhoogde kalium of bilirubien in die bloed,
- verlaagde hemoglobien, hematokrit, leukosiete en trombosiete (bloedselle en plaatjies),
- verhoogde ESR (’n bloedtoets om inflammasie in die liggaam te meet).

Nuwe-effekte met ’n obekende frekwensie:

- slegte spierbeheer wat lomp vrywillige bewegings insluit,
 - senuweeagtigheid, slaperigheid,
 - ’n sindroom wat koors, gewrigstyfheid/ pyn, gesig- en nierversteuring, inflammasie van die bloedvate, veluitslag en velversteurings, hoë vlak van siektebestrydende witbloedselle en inflammasiemerker in jou bloed kan insluit,
 - ’n swakheid en vinnige moegheid van spiere onder vrywillige beheer.
- Indien jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aanmeld aan SAHPRA deur die vorm: **“6.04 Adverse Drug Reaction Reporting Form”**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur nuwe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van BIO CAPTOPRIL te verskaf.

5. Hoe om BIO CAPTOPRIL te bewaar

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar teen of benede 25 °C, in ’n droë plek.
- Hou die tablette in die oorspronklike houer totdat benodig word vir gebruik.
- Beskerm teen lig en vog.
- Moenie gebruik na die vervaldatum wat op die buitenste karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat BIO CAPTOPRIL bevat:

Die aktiewe stof is kaptopril. Die tablette word in twee sterktes vervaardig: 12,5 mg en 25 mg.

Die ander bestandele is kolloïdale silikondioksied, watervrye laktose, mikrokristallyne sellulose, palmitiesuur, stysel en talk.

Hoe BIO CAPTOPRIL lyk en inhoud van die pak

BIO CAPTOPRIL 12,5 mg: Wit tot naaswit, ronde, plat, afgeronde rante tablet, met ’n breeklyn gedruk aan een kant, ongedruk aan die ander kant.
BIO CAPTOPRIL 25 mg: Wit tot naaswit gekleurde, ronde, plat skuins rande, onbedekte tablette, glad aan die een kant en kruislynmerke aan die ander kant, vry van krake, vlekke en breke in die tabletoppervlak.
BIO CAPTOPRIL 12,5 mg en BIO CAPTOPRIL 25 mg word verpak in wit HDPE houers met 60 tablette.

Houer van die Sertifikaat van Registrasie

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Hierdie pamflet is laas hersien op

01 Junie 2023

Registrasienuommer

BIO CAPTOPRIL 12,5 mg: 31/7.1/0657

BIO CAPTOPRIL 25 mg: 31/7.1/0658

Botswana	
Reg. Nr. BOT0600858	52

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