

## SCHEDULING STATUS:

S3

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

BIO CAPTOPRIL 12,5 mg (Each tablet contains 12,5 mg captopril).

BIO CAPTOPRIL 25 mg (Each tablet contains 25 mg captopril).

### Please read this leaflet carefully before using BIO CAPTOPRIL tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- 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.

### 1. WHAT BIO CAPTOPRIL CONTAINS:

The active substance is captopril.

*The tablets come in the following different strengths:* 12,5 mg, 25 mg and 50 mg

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

Contains sugar (lactose anhydrous). BIO CAPTOPRIL 25 mg contains 52,00 mg lactose anhydrous and BIO CAPTOPRIL 12,5 mg contains 26,00 mg lactose anhydrous.

### 2. WHAT BIO CAPTOPRIL 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.

### 3. BEFORE YOU TAKE BIO CAPTOPRIL:

#### Do not take BIO CAPTOPRIL:

- if you are you pregnant or planning to become pregnant
- if you are you breastfeeding
- if you are hypersensitive (allergic) to captopril or to any of the other ingredients of BIO CAPTOPRIL, or to any other medicines
- if you have 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 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
- if you are taking diuretics (waterpills) such as amiloride, spironolactone, triamterene
- if you have Addison's disease
- if you are taking lithium

### Take special care with BIO CAPTOPRIL:

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.

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.

### Taking 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.

### Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional 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 machinery:

BIO CAPTOPRIL tablets do not usually affect your ability to drive. However, if you feel light-headed or dizzy, do not drive and check with your doctor.

### Important information about some of the ingredients of BIO CAPTOPRIL:

BIO CAPTOPRIL contains lactose. BIO CAPTOPRIL should not be taken by patients who have inherited problems such as an intolerance to some sugars, Lapp lactase deficiency (this is when the body is unable to digest milk or milk products due to lack of an enzyme) or glucose-galactose malabsorption (this is when the small intestine is unable to absorb and transport the sugars glucose and galactose).

### Taking other medicines with BIO CAPTOPRIL:

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

These include medicines from pharmacies for colds, coughs, hay fever or sinus problems as these may increase your blood pressure. If you are also taking anti-inflammatory painkillers (e.g. indomethacin, ibuprofen), lithium, allopurinol (treatment for gout), procainamide (a treatment for irregular heartbeats), some of the older antidepressants, antipsychotics, immunosuppressants (e.g. azathioprine and cyclophosphamide), potassium supplements, salt substitutes containing potassium, other products which can increase potassium in your body, such as heparin, or any other treatment for high blood pressure, including water tablets, remind your doctor before taking BIO CAPTOPRIL.

### 4. HOW TO TAKE BIO CAPTOPRIL:

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

Always use BIO CAPTOPRIL exactly as your doctor has instructed you. Do not take more or less tablets and do not take them more often than recommended. You should check with your doctor or pharmacist if you are unsure. 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.

The usual starting dose for the treatment of high blood pressure is 12,5 – 25 mg twice 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. The usual test dose after a heart attack 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.

### 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 control 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.

### 5. 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 while taking BIO CAPTOPRIL, please consult your doctor, pharmacist or other health care professional for advice.

### If you experience any of the following STOP TAKING YOUR MEDICINE AND TELL YOUR DOCTOR IMMEDIATELY:

Swelling of the hands, face, lips or tongue, difficulty in breathing, sore throat or fever, severe dizziness or fainting, severe abdominal pain, unusually fast or irregular heart beat jaundice (yellow skin/eyes), a sudden, unexplained rash or burning, red or peeling skin.

Sometimes BIO CAPTOPRIL causes dizziness, itching, hair loss, flushing, cold extremities, taste impairment, dry mouth, anorexia, upset stomach, sickness, abdominal pain, diarrhoea or constipation, pins and needles, cough and swollen glands, sleep disorders, drowsiness, headache, feeling generally unwell. If these symptoms persist or become troublesome you should tell your doctor.

Sometimes patients may feel dizzy after taking the first one or two doses of BIO CAPTOPRIL. If this happens to you, lie down till these symptoms disappear. Disorders of the blood, kidney or liver can occur less frequently. Your doctor may need to give you blood or urine tests to monitor your condition.

### Less frequently the following have been reported to occur:

confusion, depression, blurred vision, runny nose, chest pain, heart attack, stroke, stomach ulcers, skin disorders, including pale skin, sensitivity of the skin to light, sore mouth and mouth ulcers, pains in the muscles and joints, impotence, swelling of the breasts, fatigue, chemical and blood sugar changes. If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### 6. STORING AND DISPOSING OF BIO CAPTOPRIL:

- 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.
- KEEP OUT OF REACH OF CHILDREN
- 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)

### 7. PRESENTATION OF BIO CAPTOPRIL:

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

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

### 8. IDENTIFICATION OF BIO CAPTOPRIL:

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 uncoated tablet, with a cross-line marking on one side and plain on the other side.

### 9. REGISTRATION NUMBER:

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

BIO CAPTOPRIL 25 mg: 31/7.1/0658

### 10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Biotech Laboratories (Pty) Ltd.  
Ground Floor, Block K West, Central Park  
400 16<sup>th</sup> Road, Randjespark, Midrand, 1685  
South Africa  
Tel: (011) 848 3050

### 11. DATE OF PUBLICATION:

Date of Registration

BIO CAPTOPRIL 12,5 mg: 27 July 1998

BIO CAPTOPRIL 25 mg: 18 February 1998

Date of latest revision of the text as approved by Council: 17 April 2009

Date of editorial corrections: 28 February 2019

Botswana Reg. No. BIO CAPTOPRIL 25 mg: BOT0600858	S2
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## SKEDULERING STATUS:

[S3]

### HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:

BIO CAPTOPRIL 12,5 mg (Elke tablet bevat 12,5 mg kaptopriël).  
BIO CAPTOPRIL 25 mg (Elke tablet bevat 25 mg kaptopriël).

### Lees hierdie inligtingsblad aandagtig voordat BIO CAPTOPRIL tablette gebruik word.

- Bewaar hierdie inligtingsblad, Dit mag nodig wees om dit weer te lees.
- Indien u enige verdere vrae het, raadpleeg u dokter of apteker.
- BIO CAPTOPRIL is vir u persoonlik voorgeskryf en u moet nie die medisyne met ander persone deel nie. Dit mag skadelik vir hul wees, selfs as hul simptome dieselfde is as wat u ervaar.

### 1. WAT BIO CAPTOPRIL BEVAT:

Die aktiewe bestandele is kaptopriël. Die tablette het die volgende verskeie sterktes: 12,5 mg, 25 mg and 50 mg  
Die ander bestandele is watervrye laktose, mikrokristalliene sellulose, stysel, palmitiesuur, kolloidale silikondioxiëd en talk.  
Bevat suiker (watervrye laktose). BIO CAPTOPRIL 25 mg bevat 52,00 mg watervrye laktose en BIO CAPTOPRIL 12,5 mg bevat 26,00 mg watervrye laktose.

### 2. WAARVOOR BIO CAPTOPRIL GEBRUIK WORD:

Kaptopriël is 'n lid van die groep medisyne bekend as Angiotensien-omskakelende ensiem (ACE) remmers. ACE-remmers verminder konstruksie van bloedvate, wat die bloedvloei deur die vate vergemaklik.  
BIO CAPTOPRIL word gebruik om bloeddruk te verlaag en/of te help met behandeling van mense met hartversaking.

### 3. VOORDAT U BIO CAPTOPRIL NEEM:

#### Moet nie BIO CAPTOPRIL neem:

- as u swanger is of beplan om swanger te raak nie
- as u borsvoed
- indien u hipersensitiwiteit teenoor kaptopriël of enige van die ander bestandele van BIO CAPTOPRIL, of enige ander medisyne het nie
- as u al ooit 'n reaksie wat swelling van die hande, gesig, lippe of tong, ervaar het wat veroorsaak is deur medisyne of waar die oorsaak onbekend is nie
- indien u 'n oorerflike toestand vanaf u ouers het wat swelling van die hande, gesig, lippe of tong behels
- indien u 'n vernouing van die aortiese klep het
- indien u 'n harttoestand het waar die hart vergroet is
- indien u ingeperkte nierfunksie of vernouing van die nierbuise het
- as u diuretika (waterpille) neem, soos amiloried, spironolaktoon, triamteren.
- As u Addison siekte het
- Indien u litium neem

### Neem spesiale sorg met BIO CAPTOPRIL:

Dit is in seldsame gevalle gevind dat BIO CAPTOPRIL die bloedsuiker-verlagings effek van sekere anti-diabetiese medisyne kan verhoog. Dit kan gebeur in die eerste paar weke van behandeling. Indien dit gebeur, kontak u dokter wat sal besluit of aanpassing van u dosering van anti-diabetiese medisyne nodig is.  
Allergiese tipe reaksies is al aangemeld wanneer persone wat medisyne soos BIO CAPTOPRIL gebruik dialiese ondergaan. Lig u dokter in voor u volgende dialiese behandeling.

### Neem van BIO CAPTOPRIL met voedsel en drank:

Matige hoeveelhede alkohol sal nie BIO CAPTOPRIL affekteer nie. U moet egter met u dokter bevestig of gebruik van drank vir u aanbeveel word.

### Swangerskap en borsvoeding:

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of enige ander gesondheidsorgwerker vir advies voordat u BIO CAPTOPRIL neem.  
Die is nie veilig om BIO CAPTOPRIL te neem gedurende swangerskap of borsvoeding nie. U moet u dokter inlig as u swanger raak of beplan om swanger te raak tydens behandeling met BIO CAPTOPRIL.

### Bestuur en gebruik van masjinerie:

BIO CAPTOPRIL tablette beïnvloed nie normaalweg u vermoë om te bestuur nie. As u egter lighoofdig of duiselig voel, moet nie bestuur nie en raadpleeg u dokter.

### Belangrike inligting oor sommige van die bestandele van BIO CAPTOPRIL:

BIO CAPTOPRIL bevat laktose. BIO CAPTOPRIL moet nie geneem word deur pasiënte met oorerflike probleme soos onverdraagsaamheid teenoor sekere suikers nie. Lapp-laktase ontoereikendheid (dit is as die liggaam nie die vermoë het om melk of melkprodukte te verteer nie, as gevolg van 'n gebrek aan sekere ensieme) of glukose-galakotse wanabsorpsie (dit is wanneer die klein ingewande nie die suikers, glukose of galakotse kan absorbeer of vervoer nie).

### Neem van BIO CAPTOPRIL saam met ander medisyne:

Lig altyd u gesondheidsorg professionele persoon in, indien u enige ander medisyne neem. (Dit sluit komplimentêre of tradisionele medisyne in).  
Dit sluit ook medisyne vanuit die apteek soos verkoue, hoës, hooikoors of sinus probleme in, omdat hierdie medisyne u bloeddruk kan verhoog. Indien u ook anti-inflammatoriese pynstillers (bv. indometasien, ibuprofen), litium, allopurinol (behandeling vir jirg), prokainamied ('n behandeling vir onreëlmatige hartklop), sommige van die ouer antidepressante, antipsigotika, immuun-onderdrukkers (bv. azatioprien en siklofosfamid), kaliuumaanvullings, soutvervangings wat kaliuim bevat, ander produkte wat die kaliuim in u liggaam kan verhoog, soos heparien, of enige ander behandeling vir hoë bloeddruk, insluitend watertablette, herinner u dokter voordat u BIO CAPTOPRIL neem.

### 4. HOE OM BIO CAPTOPRIL TE NEEM:

Moet nie medisyne wat vir u voorgeskryf is met ander persone deel nie.  
Gebruik altyd BIO CAPTOPRIL presies soos deur u dokter aanbeveel. Moet nie meer of minder tablette neem en ook nie meer gereeld as was wat aanbeveel is nie. Bevestig met u dokter of apteker indien u nie seker is nie.  
U dokter sal u inlig oor die duur van behandeling met BIO CAPTOPRIL. Indien u die indruk kry dat die effek van BIO CAPTOPRIL te sterk of te swak is, raadpleeg u dokter of apteker.  
Die gewone aanvangsdosis vir die behandeling van hoë bloeddruk is 12,5 – 25 mg twee keer per dag. U dokter mag die dosis gradueel verhoog tot 100 – 150 mg per dag. U mag ook ander medisyne benodig om u bloeddruk te verlaag.  
Ouer pasiënte en die wat nierprobleme het, kan moontlike 'n laer aanvangsdosering ontvang.  
Die gewone toets-dosis na 'n hartaanval is 6,25 mg of 12,5 mg drie keer per dag, wat dan deur u dokter verhoog kan word tot 'n maksimum van 300 mg per dag.

### Indien u meer BIO CAPTOPRIL neem as voorgeskryf:

In die geval van oordosering, raadpleeg u dokter of apteker. As beide nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.  
Indien u na die hospital gaan, neem die leë houër en enige oorblywende tablette saam met u. Indien die persoon flou geword het, laat hul neerleë en lig hul voete hoër as hul kop.

### Indien u vergeet om u BIO CAPTOPRIL te neem:

As u vergeet om 'n dosis te neem, neem dit sodra u onthou. Moet nie 'n dubbele dosis neem om op te maak vir die vergete individuele dosis nie. Gaan voort om die volgende tablet te neem op die gewone tyd.

### 5. MOONTLIKE NEWE-EFFEKTE:

BIO CAPTOPRIL kan verskeie nuwe-effekte hê. Nie alle nuwe-effekte aangemeld vir BIO CAPTOPRIL word in hierdie inligtingsblad genoem nie. Indien u algemene gesondheid verswak terwyl u BIO CAPTOPRIL neem, raadpleeg u dokter, apteker of enige ander gesondheidsorg professionele persoon vir advies.

### Indien u enige van die volgende ondervind STAAK DIE MEDISYNE EN LIG U DOKTER ONMIDDELIK in:

Swelling van die hande, gesig, lippe en tong, probleme met asemhaling, seer keel of tong, erge duiseligheid of floute, erge abdominale pyn, ongewone vinnige of onreëlmatige hartklop, geelsug (geel vel/oë), 'n skielike, onverklaarbare uitslag of brandende, rooi of afskilferende vel.

BIO CAPTOPRIL kan soms die volgende veroorsaak: duiseligheid, jeuk, haarverlies, blosing, koue ledemate, siekte, smaak- verandering, droë mond, anoreksie, omgekrapte maag, naarheid, abdominale pyn, diarree of hardlywigheid, naalde en spelde, hoës en geswelde kliere, slaapversteurings, duiseligheid, hoofpyn, algemene siekerige gevoel. Indien hierdie simptome volhou of kommerwekkend word, lig u dokter in.  
Soms vol pasiënte duiselig na die eerste een of twee dosisse van BIO CAPTOPRIL. Indien dit met u gebeur, gaan lê totdat die simptome verdwyn.  
Versteurings van die bloed, niere of lewer kan minder algemeen voorkom. Dit mag dalk vir u dokter nodig wees om bloed of uriene toetse te doen om u toestand te monitor.

### Die volgende is minder algemeen aangemeld:

verwarring, depressie, versteurde visie, loopneus, borspyn, hartaanval, beroerte, maagere, velversteurings, insluitend bleek vel, sensitiwiteit van die vel teenoor lig, seer mond of mondkulke, pyn in die spiere of gewrigte, impotensie, swelling van die borste, moegheid, chemiese en bloedsuiker verandering.  
Indien u enige nuwe-effekte wat nie in hierdie inligtingsblad genoem word nie, opmerk, lig u dokter of apteker in.

### 6. BEWARING EN VERNIETIGING VAN BIO CAPTOPRIL:

- Bewaar teen of benede 25 °C, in 'n droë plek.
- Bewaar die tablette in die oorspronklike houër tot benodig vir gebruik.
- Beskerm teen lig en vog.
- HOU BUITE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum soos aangedui op die karton nie.
- Handig alle ongebruikte medisyne vir u apteker in
- Moet nie ongebruikte medisyne in 'n drein of rioolstelsels wegspoel nie (bv.toilette)

### 7. AANBIEDING VAN BIO CAPTOPRIL:

BIO CAPTOPRIL 12,5 mg is verpak in sekuriteitshouers wat 100 tablette bevat.  
BIO CAPTOPRIL 25 mg is verpak in sekuriteitshouers wat 60 tablette bevat.

### 8. IDENTIFIKASIE VAN BIO CAPTOPRIL:

BIO CAPTOPRIL 12,5 mg: 'n Wit of naaswit, ronde, gewone tablet met 'n skuins rand en gebosselleerde breeklyn aan een kant. Die ander kant is gewoon.  
BIO CAPTOPRIL 25 mg: 'n Wit of naaswit, ronde, gewone onbedekte tablet met 'n gebosselleerde skuins rand, 'n kruislyn merk aan een kant en gewoon aan die ander kant.

### 9. REGISTRASIE NOMMER:

BIO CAPTOPRIL 12,5 mg: 31/7.1/0657  
BIO CAPTOPRIL 25 mg: 31/7.1/0658

### 10. NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT:

Biotech Laboratories (Edms) Bpk.  
Grond Vloer, Blok K Wes, Central Park  
400 16<sup>de</sup> Weg, Randjespark, Midrand, 1685  
Suid Afrika  
Tel: (011) 848 3050

### 11. DATUM VAN PUBLIKASIE:

Datum van registrasie:  
BIO CAPTOPRIL 12,5 mg: 27 Julie 1998  
BIO CAPTOPRIL 25 mg: 18 Februarie 1998  
Datum van die laaste hersiening van die teks soos goedgekeur deur die Raad:  
17 April 2009  
Datum van redaksionele regstellings: 28 Februarie 2019

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