ENALAPRIL BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ENALAPRIL 5 BIOTECH tablets
ENALAPRIL 10 BIOTECH tablets
ENALAPRIL 20 BIOTECH tablets
Enalapril maleate
Contains sugar (lactose monohydrate: 232,00 mg per 5 mg tablet, 142,00 mg per 10 mg tablet and 284,00 mg per 20 mg tablet).

Read all of this leaflet carefully before you start taking ENALAPRIL BIOTECH.
- 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.
- ENALAPRIL BIOTECH 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 ENALAPRIL BIOTECH is and what it is used for
2. What you need to know before you take ENALAPRIL BIOTECH
3. How to take ENALAPRIL BIOTECH
4. Possible side effects
5. How to store ENALAPRIL BIOTECH
6. Contents of the pack and other information

1. What ENALAPRIL BIOTECH is and what it is used for

Enalapril maleate, the active ingredient of ENALAPRIL BIOTECH, belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.
It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

ENALAPRIL BIOTECH is used to treat:
- High blood pressure - treating high blood pressure (hypertension) in adult patients.
- Heart failure - treating adult heart failure patients with reduced heart muscle function (where your heart has difficulty pumping blood through your body).

2. What you need to know before you take ENALAPRIL BIOTECH

Do not take ENALAPRIL BIOTECH:
- If you are allergic (hypersensitive) to enalapril maleate or to any of the other ingredients of ENALAPRIL BIOTECH (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous angiotensin II receptor blockers/antagonists (ARB) or angiotensin converting enzyme (ACE) inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema).
- If you have a serious heart disease called, hypertrophic obstructive cardiomyopathy.
- If you have aortic stenosis (narrowing of the main heart valve leading from the heart);
- If you have hypertrophic cardiomyopathy (heart muscle disease);
- If you have renal artery stenosis (narrowing of the artery supplying the kidney with blood);
- If you only have a single kidney and it has a narrow artery.
- If you are also using "water tablets" (diuretics) called potassium sparing diuretics.
- Porphyria
- If you have severe kidney function impairment.
- Concomitant use (that is to use at the same time), of fluoroquinolones (a type of antibiotic) with an ACE inhibitors (this specific type of medication), is contraindicated in patients suffering kidneys not functioning well.
- If you are taking lithium tablets (which have been prescribed to you by your doctor).
- If you are taking medicines containing aliskiren used to lower your blood pressure.
- If you are taking the combination medicine sacubitril/valsartan to treat heart failure.

If you are not sure if any of the above applies to you, please talk to your doctor.

Warnings and precautions

Should you become pregnant while taking ENALAPRIL BIOTECH tablets, you must stop the treatment immediately and see you doctor. Your doctor will need to prescribe an alternative medicine to ENALAPRIL BIOTECH for you. If you are trying to become pregnant, you must ask your doctor to switch you to an alternative medicine for your specific condition.

ENALAPRIL BIOTECH should be used with caution in the following conditions:
- If you have a heart condition or a history thereof.
- If you have a kidney problem (the kidneys are not functioning as they should).
- If you are suffering or have previously suffered a stroke.
- If you are vomiting, have recently had severe vomiting, or have diarrhoea.
- If you are on a salt restricted diet.
- If you are taking other medication or supplements that might contain potassium or elevate your potassium levels in your body.
- Elderly patients with heart conditions are at higher risk to develop kidney failure.
- If you have recently had a kidney transplant.
- Patients with bone marrow depression have an increased risk for developing other infections due to a suppressed immune system. Your doctor may occasionally do blood tests to check whether ENALAPRIL BIOTECH has had any effect on your blood.
- If you are suffering from a persistent dry cough, you should contact your doctor. Alternative treatment may be required for your condition.
- If you have suffered a heart attack, you need to monitor your blood pressure during treatment with ENALAPRIL BIOTECH.
- Taking ENALAPRIL BIOTECH with oral anti-diabetic tablets or with insulin injections can cause a severe drop in your blood sugar levels. Caution is advised if you are suffering from diabetes.
- Allergic reactions to ENALAPRIL BIOTECH can be life threatening. If you experience swelling of the face, lips or tongue with difficulty breathing, you must go to the emergency unit at the nearest hospital.
- If you have to undergo surgery and have to receive an anaesthetic (the combination of ENALAPRIL BIOTECH and an anaesthetic may cause your blood pressure to drop extremely low).
- If you are receiving treatment to reduce your reaction to bee and wasp stings.
- 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.
- If you have a liver problem. If you experience jaundice (a condition in which the skin, whites of the eyes and mucous membranes turn yellow). Tell your doctor immediately if this happens.
- If you are taking any of the following medicines, the risk of angioedema may be increased:
  - Racecadotril, amedicine used to treat diarrhoea.
  - Medicines used to prevent organtrans plant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
  - Vildagliptin, amedicine used to treat diabetes.
- If you are taking any of the following medicines used to treat high blood pressure:
  - anangiotensin II receptor blocker (ARB) (also known as sartans-for example valsartan, telmisartan, irbesartan, etc.), in particular if you have diabetes-related kidney problems.
  - aliskiren.
- If you are taking the combination medicine sacubitril/valsartan to treat heart failure. Your doctor will tell you when you can start taking ENALAPRIL BIOTECH after stopping your treatment with sacubitril/valsartan.

Children

ENALAPRIL BIOTECH should not be used in children.

Other medicines and ENALAPRIL BIOTECH

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
If you are using certain medicines, your doctor may need to do blood tests from time to time.

ENALAPRIL BIOTECH may interact with the following medicines:
- An angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take ENALAPRIL BIOTECH" and "Warnings and precautions").
- Other medicines to help lower your blood pressure, including beta blockers, methyldopa, calcium channel blockers.
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Water tablets (diuretics).
- Medicines for diabetes (including oral antidiabetic medicines and insulin).
- Non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation)
- Muscle relaxant medicine to treat muscle or joint stiffness or some medicine used to treat rheumatoid arthritis including gold salts therapy such as sodium aurothiomalate.
- Ciclosporin (immunosuppressant therapy used after organ transplant to prevent organ rejection) used together with ENALAPRIL BIOTECH may lead to increased levels of potassium in your blood.
- Antacids may reduce the absorption of ENALAPRIL BIOTECH and must preferably be taken at least two hours apart.
- Lithium (a medicine for mental health problems).
- Medicines for depression called tricyclic antidepressants.
- Medicines for mental problems called antipsychotics.
- Antibiotics - the fluoroquinolones, as they may cause serious kidney problems.
- Other medicines to help lower your blood pressure, including beta blockers, methyldopa, calcium channel blockers.
- Certain cough and cold medicines and weight reducing medicines which contain something called a sympathomimetic medicine.
- An mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus; medicines used to treat certain types of cancer or to prevent the body's immune system from rejecting a transplanted organ). See also information under the heading "Warnings and precautions".
- The combination medicine sacubitril/valsartan, racecadotril or vildagliptin. The risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased. See also information under the headings "Do not take ENALAPRIL BIOTECH" and "Warnings and precautions".
- Alcohol.

ENALAPRIL BIOTECH with food and drink

ENALAPRIL BIOTECH can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby do not take ENALAPRIL BIOTECH. Your doctor will change your medication to an alternative safer option. ENALAPRIL BIOTECH can cause serious harm to your baby. Consult your doctor immediately if you become pregnant or plan to become pregnant while taking ENALAPRIL BIOTECH.
Tell your doctor if you are breastfeeding or about to start breastfeeding.
ENALAPRIL BIOTECH is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

After taking ENALAPRIL BIOTECH, make sure that you are well enough to drive or operate machinery. Some people may feel tired or dizzy when taking ENALAPRIL BIOTECH.

ENALAPRIL BIOTECH contains lactose monohydrate

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

3. How to take ENALAPRIL BIOTECH

Do not share medicines prescribed for you with any other person.
Always take ENALAPRIL BIOTECH exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
If you have the impression that the effect of ENALAPRIL BIOTECH is too strong or too weak, talk to your doctor or pharmacist.
It is important to keep taking ENALAPRIL BIOTECH every day. You can take ENALAPRIL BIOTECH with or without food.
Swallow the tablet with a drink of water. 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 starting dose of ENALAPRIL BIOTECH is 10 mg once a day. Your doctor may increase this dose to 20 mg once a day depending on blood pressure response.

Heart failure:
- The initial dose of ENALAPRIL BIOTECH is 2,5 mg (half a 5 mg tablet) and your doctor will monitor you closely to determine the initial effect on your blood pressure.
- If ENALAPRIL BIOTECH is effective and you do not experience serious side-effects, the dose may be increased gradually, according to your doctor's instructions, to the usual maintenance dose of 20 mg, given in a single dose or two divided doses.

If you take more ENALAPRIL BIOTECH than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and any remaining tablets with you, so that your doctor knows what you have taken.

General symptoms of overdosage may include:
- Very low blood pressure (therefore feeling dizzy or faint, sweaty, nausea; pale skin).
- Kidneys not functioning well.
- Fast heartbeat or irregular heartbeat (palpitations), slow heartbeat.
- Shortness of breath or struggling to breathe, anxiety.

If you forget to take ENALAPRIL BIOTECH

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before.
Do not take two dosages at the same time.

If you stop taking ENALAPRIL BIOTECH

If you stop taking ENALAPRIL BIOTECH, your blood pressure may increase again.
Do not stop taking ENALAPRIL BIOTECH without first talking to your doctor.
If you have any further questions on the use of ENALAPRIL BIOTECH, please ask your doctor or pharmacist.

4. Possible side effects

ENALAPRIL BIOTECH can have side effects.
Not all side effects reported for ENALAPRIL BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ENALAPRIL BIOTECH, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving ENALAPRIL BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat; swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing; severe itching of the skin (with raised lumps).
- ENALAPRIL BIOTECH may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever.
- Feeling extremely dizzy, fainting or hearing a ringing sound in your ears. This will occur because your blood pressure dropped too low.
- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ENALAPRIL BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:
- Feeling dizzy/spinning sensation.
- Feeling weak (asthenia).
- Feeling sick (nausea).
- Blurred vision.
- Cough.
- Light-headedness due to low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain.
- Depression.
- Headache, changes in your sense of taste.
- Diarrhoea, abdominal pain.
- Tiredness (fatigue).
- High levels of potassium in the blood, increased levels of creatinine in your blood (both are usually detected by a test).
- Heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain).
- Stroke (possibly due to very low blood pressure in high-risk patients).

The following side effects have been reported less frequently:
- Flushing.
- Sudden fall in blood pressure.
- Fast or uneven heart beats (palpitations).
- Anaemia (including aplastic and haemolytic).
- Confusion, sleeplessness or sleepiness, nervousness.
- Feeling your skin prickling or being numb.
- Vertigo (spinning sensation).
- Ringing in your ears (tinnitus).
- Runny nose, sore throat or hoarseness.
- Asthma-associated tightness in chest.
- Slow movement of food through your intestine (ileus), inflammation of your pancreas.
- Being sick (vomiting), indigestion, constipation, anorexia.
- Irritated stomach (gastric irritations), dry mouth, ulcer.
- Muscle cramps.
- Impaired kidney function, kidney failure.
- Increased sweating.
- Itching, rash or hives.
- Hair loss.
- Generally feeling unwell (malaise), high temperature (fever).
- Impotence.
- High level of proteins in your urine (measured in a test).
- Low level of blood sugar or sodium, high level of blood urea (all measured in a blood test).
- Raynaud's phenomenon where your hands and feet may become very cold and white due to low blood flow.
- Changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- Bone marrow depression.
- Swollen glands in neck, armpit or groin.
- Autoimmune diseases.
- Strange dreams or sleep problems.
- Accumulation of fluid or other substances in the lungs (as seen on X-rays).
- Inflammation of your nose.
- Inflammation of the lungs causing difficulty breathing (pneumonia).
- Inflammation of the cheeks, gums, tongue, lips, throat.
- Reduced amount of urine.
- Rash with a bullseye pattern (erythema multiforme).
- Stevens-Johnson syndrome and toxic epidermal necrolysis (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin).
- Liver or gallbladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), high levels of liver enzymes or bilirubin (measured in a blood test).
- Enlargement of breasts in males (gynaecomastia).
- Swelling in your intestine (intestinal angioedema).

Other side effects (frequency unknown):
- Overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion.
- A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity or other skin manifestations may occur.

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. 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 ENALAPRIL BIOTECH.

5. How to store ENALAPRIL BIOTECH
- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original packaging until use, to protect from moisture.
- Do not store in your bathroom, to limit the contact with moisture in the surrounding air.
- Do not take your tablets after the expiry date stated on the container or outer carton.
- Please return all unused or expired medicines to your pharmacist and do not dispose of these medicines in drains or sewerage systems (via wastewater or household waste).

6. Contents of the pack and other information

What ENALAPRIL BIOTECH contains

Each ENALAPRIL 5 BIOTECH tablet contains 5 mg enalapril maleate.
Each ENALAPRIL 10 BIOTECH tablet contains 10 mg enalapril maleate.
Each ENALAPRIL 20 BIOTECH tablet contains 20 mg enalapril maleate.

The other ingredients are:

ENALAPRIL 5 BIOTECH: croscarmellose sodium, ferric oxide (red), lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch and sodium hydrogen carbonate.
ENALAPRIL 10 and BIOTECH ENALAPRIL 20 BIOTECH: croscarmellose sodium, ferric oxide (black), ferric oxide (red), lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch and sodium hydrogen carbonate.

What ENALAPRIL BIOTECH looks like and contents of the pack:

ENALAPRIL 5 BIOTECH: Pink, mottled, round, flat tablets with bevelled edges, debossed with "ELP 5" on one side and scored on the other side.
ENALAPRIL 10 BIOTECH: Brownish-pink, mottled, round, flat tablets with bevelled edges, debossed with "ELP 10".
ENALAPRIL 20 BIOTECH: Greyish-violet, mottled, round, flat tablets with bevelled edges, debossed with "ELP 20".
Aluminium foil blister packs containing 20, 30 and 90 tablets.

Holder of the certificate of registration

Biotech Laboratories (Pty) Ltd
Ground Floor Block K West Central Park
400 16th Road, Randjespark
Halfway House
Midrand 1685
Tel no.: +27 (0) 11 848 3050

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ENALAPRIL BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S3

ENALAPRIL 5 BIOTECH tablette
ENALAPRIL 10 BIOTECH tablette
ENALAPRIL 20 BIOTECH tablette
Enalaprilmaleaat
Bevat suiker (laktosemonohidraat: 232,00 mg per 5 mg tablet, 142,00 mg per 10 mg tablet and 284,00 mg per 20 mg tablet).

Lees die hele pamflet noukeurig deur voordat jy begin om ENALAPRIL BIOTECH te neem
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- ENALAPRIL BIOTECH is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander persone deel nie. Dit kan hulle skade aandoen, al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat ENALAPRIL BIOTECH is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy ENALAPRIL BIOTECH neem
3. Hoe om ENALAPRIL BIOTECH te neem
4. Moontlike newe-effekte
5. Hoe om ENALAPRIL BIOTECH te bewaar
6. Inhoud van die pak en ander inligting

1. Wat ENALAPRIL BIOTECH is en waarvoor dit gebruik word
Enalaprilmaleaat, die aktiewe bestanddeel van ENALAPRIL BIOTECH, behoort aan 'n groep medisyne wat angiotensienomskakelingsensiem (ACE) inhibeerders genoem word.
Dit werk deur jou bloedvate te laat ontspan en verbreed. Dit help om jou bloeddruk te verlaag. Dit maak dit ook makliker vir jou hart om bloed na alle dele van jou liggaam te pomp.

ENALAPRIL BIOTECH word gebruik om die volgende te behandel:
- Hoë bloeddruk – behandeling van hoë bloeddruk (hipertensie) in volwasse pasiënte.
- Hartversaking – behandeling van volwasse hartversakingspasiënte met verlaagde hartspierfunksie (waar jou hart sukkel om bloed deur jou liggaam te pomp).

2. Wat jy moet weet voordat jy ENALAPRIL BIOTECH neem
Moenie ENALAPRIL BIOTECH neem nie:
- Indien jy allergies (hipersensitief) is vir enalaprilmaleaat of vir enige van die ander bestanddele van ENALAPRIL BIOTECH is (gelys in afdeling 6).
- Indien jy swanger is of borsvoed.
- Indien jy simptome ervaar soos hyg, swelling van die gesig, tong of keel, intense jeuk of erge veluitslag met vorige angiotensien II-reseptorblokkers/ antagoniste (ARB) of angiotensien omskakelende ensiem (ACE) inhibeerderbehandeling of as jy of 'n lid van jou familie hierdie simptome in enige ander omstandighede gehad het ('n toestand genaamd angioedeem).
- Indien jy 'n ernstige hartsiekte het genaamd hipertrofiese obstruktiewe kardiomiopatie.
- Indien jy aortastenose het (vernouing van die hoofhartklep wat vanaf die hart lei);
- Indien jy hipertrofiese kardiomiopatie het (hartspiersiekte);
- Indien jy renale arterie stenose het (vernouing van die arterie wat die nier van bloed voorsien);
- Indien jy slegs een nier het en dit 'n noue arterie het.
- Indien jy ook "watertablette" (diuretika) neem genaamd kaliumsparende diuretika.
- Porfirie
- Indien jy ernstige lewerfunksie ontoereikendheid het.
- Gelyktydige gebruik (wanneer jy dit op dieselfde tyd gebruik) van fluorokinolone ('n tipe antibiotika) met 'n ACE inhibeerder (hierdie spesifieke tipe medikasie) is teenaangedui in pasiënte wie se niere nie goed funksioneer nie.
- Indien jy litiumtablette neem (wat vir jou voorgeskryf is deur jou dokter).
- Indien jy medisyne neem wat aliskiren bevat wat gebruik word om jou bloeddruk te verlaag.
- Indien jy die kombinasie medisyne sakubitriel/ valsartan neem om hartversaking te behandel.

Indien jy nie seker is of enige van die bogenoemde op jou van toepassing is nie, praat asseblief met jou dokter.

Waarskuwings en voorsorgmaatreëls

Indien jy sou swanger raak terwyl jy ENALAPRIL BIOTECH tablette neem, moet jy onmiddelik ophou om die behandeling te neem en jou dokter gaan sien. Jou dokter sal vir jou 'n alternatiewe medisyne vir ENALAPRIL BIOTECH vir jou voorskryf. Indien jy probeer om swanger te raak moet jy jou dokter vra om jou na 'n alternatiewe medisyne vir jou spesifieke toestand oor te skakel.

ENALAPRIL BIOTECH moet met omsigtigheid gebruik word in die volgende toestande:
- Indien jy 'n harttoestand het of 'n geskiedenis daarvan het.
- Indien jy 'n nierprobleem het (die niere funskioneer nie soos hulle moet nie).
- Indien jy 'n beroerte het of al 'n beroerte gehad het.
- Indien jy braak of onlangs erge braking gehad het of diarree het.
- Indien jy op 'n soutbeperkde dieet is.
- Indien jy ander medisyne of aanvullings neem wat kalium bevat of wat jou kaliumvlakke in jou liggaam verhoog.
- Bejaarde pasiënte met harttoestande loop 'n hoër risiko om nierversaking te ontwikkel.
- Indien jy onlangs 'n nieroorplanting gehad het.
- Pasiënte met beenmurgonderdrukking loop 'n verhoogde risiko om ander infeksies te ontwikkel as gevolg van 'n onderdrukte immuunsisteem. Jou dokter mag af en toe bloedtoetse doen om te sien of ENALAPRIL BIOTECH enige effek op jou bloed het.
- Indien jy 'n aanhoudende, droë hoes het moet jy jou dokter kontak. Alternatiewe behandeling mag nodig wees vir jou toestand.
- Indien jy 'n hartaanval gehad het moet jy jou bloeddruk monitor gedurende behandeling met ENALAPRIL BIOTECH.
- Die neem van ENALAPRIL BIOTECH saam met orale anti-diabetiese tablette of met insulien inspuitings kan 'n ernstige verlaging in jou bloedsuikervlakke veroorsaak. Wees versigtig indien jy aan diabetes ly.
- Allergiese reaksies vir ENALAPRIL BIOTECH kan lewensbedreigend wees. Indien jy swelling van die gesig, lippe of tong ervaar met moeilike asemhaling, moet jy na die ongevalle-afdeling gaan van jou naaste hospitaal.
- Indien jy 'n operasie moet ondergaan en 'n verdowingsmiddel ontvang (die kombinasie van ENALAPRIL BIOTECH en 'n verdowingsmiddel kan jou bloeddruk uiters laag laat daal).
- Indien jy behandeling ontvang om jou reaksie op by- en perdebysteke te verminder.
- Sommige swart pasiënte mag 'n verlaagde reaksie op hierdie tipe medisyne hê wanneer dit as die enigste behandeling gegee word. Hierdie pasiënte mag dalk 'n hoër dosis benodig.
- Indien jy 'n lewerprobleem het. Indien jy geelsug ('n toestand waar die vel, die wit van die oë en slymvliese geel word) het. Vertel onmiddelik jou dokter indien dit gebeur.
- Indien jy enige van die volgende medisyne neem mag die risiko vir angio-edeem verhoog word:
  - Rasekadotriel, 'n medisyne wat gebruik word om diarree te behandel.
  - Medisyne om orgaanoorplantings verwerping te voorkom en vir kanker (bv temsirolimus, sirolimus, everolimus).
  - Vildagliptien, 'n medisyne om diabetes te behandel.
- Indien jy enige van die volgende medisyne neem om hoë bloeddruk te behandel:
  - 'n angiotensien II reseptorblokker (ARB) (ook bekend as sartans – byvoorbeel valsartan, telmisartan, irbesartan, ens.), veral indien jy diabetesverwante nierprobleme het.
  - skirien.
- Indien jy die kombinasie van medisyne sakubitriel/ valsartan neem om hartversaking te behandel. Jou dokter sal jou vertel wanneer jy ENALAPRIL BIOTECH kan begin neem nadat jy jou behandeling met sakubitriel/ valsartaan gestaak het.

Kinders
ENALAPRIL BIOTECH moet nie in kinders gebruik word nie.

Ander medisyne en ENALAPRIL BIOTECH
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Indien jy sekere medisyne gebruik, sal jou dokter dalk van tyd tot tyd bloedtoetse moet doen.

ENALAPRIL BIOTECH kan interaksie met die volgende medisyne hê:
- 'n angiotensin II reseptor blokker (ARB) or aliskiren (sien ook die inligting onder die volgende opskrifte. "Moenie ENALAPRIL BIOTECH neem nie" en "Waarskuwings en voorsorgmaatreëls").
- Ander medisyne om te help om jou bloeddruk te verlaag, insluitend betablokkers, metieldopa, kalsiumkanaalblokkers.
- Kaliumaanvullings of sout plaasvervangers wat kalium bevat (medisyne wat die hoeveelheid kalium in jou bloed verhoog).
- Watertablette (diuretika).
- Medisyne vir diabetes (insluitende orale anti-diabetiese medisyne en insulien).
- Nie-steroïde anti-inflammatoriese medisyne (NSAIDs) soos ibuprofen, naproksen, diklofenak, selekoksib of etorikoksib (medisyne om pyn en inflammasie te verlig).
- Spierverslappermedisyne om spier- of gewrigstyfheid te behandel of een of ander medisyne wat gebruik word om rumatoïede artritis te behandel, insluitend goudsoutterapie soos natriumaurotiomalaat.
- Siklosporien (immuunonderdrukkende terapie wat gebruik word na orgaanoorplanting om orgaanverwerping te voorkom) wat saam met ENALAPRIL BIOTECH gebruik word, kan lei tot verhoogde vlakke van kalium in jou bloed.
- Teensuurmiddels mag die absorpsie van ENALAPRIL BIOTECH verlaag en moet verkieslik ten minste twee ure uitmekaar geneem word.
- Litium ('n medisyne vir geestesgesondheidsprobleme).
- Medisyne vir depressie genaamd trisikliese antidepressante.
- Medisyne vir geestesprobleme genaamd antispigotika.
- Antibiotika – die fluorokinolone, aangesien dit ernstige nierprobleme kan veroorsaak.
- Ander medisyne om te help om jou bloeddruk te verlaag, insluitende betablokkers, metieldopa, kalsiumkanaalblokkers.
- Sekere hoes en verkouemedisyne en gewigsverliesmedisyne wat iets bevat genaamd 'n simpatomimetiese medisyne.
- 'n MTOR inhibeerder (bv. temsirolimus, sirolimus, everolimus; medisyne wat gebruik word om sekere soorte kanker te behandel of om te verhoed dat die liggaam se immuunstelsel 'n oorgeplante orgaan verwerp). Sien ook inligting onder die opskrif "Waarskuwings en voorsorgmaatreëls".
- Die kombinasie medisyne sakubitriel/ valsartan, rasekadotril of vildagliptien. Die risiko van angioedeem (swelling van die gesig, lippe, tong of keel met probleme om te sluk of asem te haal) kan verhoog word. Sien ook inligting onder die opskrifte "Moenie ENALAPRIL BIOTECH neem nie" en "Waarskuwings en voorsorgmaatreëls".
- Alkohol.

ENALAPRIL BIOTECH met kos en drank
ENALAPRIL BIOTECH kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding
As jy swanger is of jou baba borsvoed, moenie ENALAPRIL BIOTECH neem nie. Jou dokter sal jou medikasie verander na 'n alternatiewe, veiliger opsie. ENALAPRIL BIOTECH kan ernstige skade aan jou baba veroorsaak. Raadpleeg jou dokter dadelik as jy swanger raak of beplan om swanger te raak terwyl jy ENALAPRIL BIOTECH neem.
Vertel jou dokter as jy borsvoed of op die punt staan om te begin borsvoed.
ENALAPRIL BIOTECH word nie aanbeveel vir moeders wat borsvoed nie, en jou dokter kan 'n ander behandeling vir jou kies as jy wil borsvoed, veral as jou baba pasgebore is, of vroeggebore is.

Bestuur en gebruik van masjiene
Nadat jy ENALAPRIL BIOTECH geneem het, maak seker dat jy goed genoeg voel om te bestuur of masjinerie te gebruik. Sommige mense kan moeg of duiselig voel nadat hulle ENALAPRIL BIOTECH neem.

ENALAPRIL BIOTECH bevat laktosemonohidraat
Indien jou dokter jou vertel het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy ENALAPRIL BIOTECH neem.

3. Hoe om ENALAPRIL BIOTECH te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd ENALAPRIL BIOTECH presies soos jou dokter jou opdrag gegee het. Indien jy onseker is, raadpleeg jou dokter of apteker.
As jy die indruk het dat die effek van ENALAPRIL BIOTECH te sterk of te swak is, praat met jou dokter of apteker.
Dit is belangrik om aan te hou om ENALAPRIL BIOTECH elke dag te neem. Jy kan ENALAPRIL BIOTECH met of sonder kos neem.
Sluk die tablet met 'n glas water. Probeer om die tablet elke dag op dieselfde tyd te neem. Dit sal jou help om te onthou om dit te neem.

Hoë bloeddruk:
- Die gewone aanvangsdosis van ENALAPRIL BIOTECH is 10 mg eenkeer per dag. Jou dokter mag hierdie dosis verhoog tot 20 mg eenkeer per dag afhangende van jou bloeddrukreaksie.

Hartversaking:
- Die aanvanklike dosis van ENALAPRIL BIOTECH is 2,5 mg ('n halwe 5 mg tablet) en jou dokter sal jou noukeurig monitor om die aanvanklike effek op jou bloeddruk te bepaal.
- Indien ENALAPRIL BIOTECH effektief is en jy nie ernstige newe-effekte ervaar nie, kan die dosis geleidelik verhoog word volgens jou dokter se opdrag tot die gewone onderhoudsdosis van 20 mg, gegee as 'n enkeldosis of twee verdeelde dosisse.

Indien jy meer ENALAPRIL BIOTECH 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.
Neem hierdie pamflet en enige oorblywende tablette saam met jou sodat jou dokter kan weet wat jy geneem het.

Algemene simptome van oordosis mag die volgende insluit:
- Baie lae bloeddruk (voel dus duiselig of flou, sweet, naarheid; bleek vel).
- Niere funskioneer nie goed nie.
- Vinnige hartklop of onreëlmatige hartklop (kloppings), stadige hartklop.
- Kortasem of sukkel om asem te haal, angs.

Indien jy vergeet om ENALAPRIL BIOTECH te neem
Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die gemiste dosis oor en gaan dan voort soos voorheen.
Moenie twee dosisse op dieselfde tyd neem nie.

Indien jy ophou om ENALAPRIL BIOTECH te neem
Indien jy ophou om ENALAPRIL BIOTECH te neem, kan jou bloeddruk weer styg.
Moenie ophou om ENALAPRIL BIOTECH te neem sonder om eers met jou dokter te praat nie.
Indien jy enige verdere vrae het oor die gebruik van ENALAPRIL BIOTECH, vra asseblief jou dokter of apteker.

4. Moontlike newe-effekte
ENALAPRIL BIOTECH kan newe-effekte hê.
Nie alle newe-effekte wat vir ENALAPRIL BIOTECH aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid versleg of indien jy enige ongewensde effekte ervaar terwyl jy ENALAPRIL BIOTECH neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om ENALAPRIL BIOTECH te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Asemhalingsprobleme met of sonder swelling van die gesig, lippe, tong en/ of keel wat probleme met sluk kan veroorsaak; erge jeuk van die vel (met verhoogde knoppe).
- ENALAPRIL BIOTECH mag 'n verlaging in die aantal witbloedselle veroorsaak. Jou weerstandigheid teen infeksie mag verlaag wees en jy mag moegheid, 'n infeksie of 'n koors opmerk.
- 'n Uiters duiselige gevoel, flou word of 'n geluid in jou ore hoor. Dit sal gebeur omdat jou bloeddruk te laag gedaal het.
- Rugpyn, pyn in gewrigte en spiere.
- Veranderinge in hoe jou lewer werk, insluitend inflammasie van die lewer (hepatitis). Jy mag dalk moegheid, vergeling van jou vel en die wit van jou oë en griepagtige simptome opmerk.

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op ENALAPRIL BIOTECH gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter indien jy van enige van die volgende kennis neem:
Die volgende newe-effekte is gereeld aangemeld:
- Duiselig gevoel/ draaiende sensasie.
- Swak gevoel (astenie).
- Siek gevoel (naarheid).
- Versteurde visie.
- Hoes.
- Lighoofdigheid as gevolg van lae bloeddruk, veranderinge in hartritme, vinnige hartklop, angina of borspyn.
- Depressie.
- Hoofpyn, veranderinge in jou smaaksintuig.
- Diarree, maagpyn.
- Moegheid.
- Hoë vlakke van kalium in die bloed, verhoogde vlakke van kreatinien in jou bloed (beide word gewoonlik opgemerk deur 'n toets).
- Hartaanval (moontlik as gevolg van baie lae bloeddruk in sekere hoërisiko pasiënte, insluitende die met bloedvloei probleme van die hart of brein).
- Beroerte (moontlik as gevolg van baie lae bloedduk in hoërisiko pasiënte).

Die volgende newe-effekte is mider gereeld aangemeld:
- Blosing.
- Skielike daling in bloeddruk.
- Vinnige of ongelyke hartklop (palpitasies).
- Bloedarmoede (anemie) (insluitende aplastiese en hemolitiese).
- Verwarring, slapeloosheid of slaperigheid, senuweeagtigheid.
- Voel hoe jou vel prikkel of gevoelloos is.
- Vertigo (spinnende sensasie).
- Lui in jou ore (tinnitus).
- Loopneus, seer keel, heesheid.
- Asma-geassosieerde styfheid in die bors.
- Stadige beweging van voedsel deur die derms (ileus), inflammasie van jou pankreas.
- Siek wees (braking), slegte spysvertering, hardlywigheid, anoreksie.
- Geïrriteerde maag (maagirritasies), droë mond, sere.
- Spierkrampe.
- Verswakte nierfunksie, nierversaking.
- Verhoogde sweet.
- Jeuk, veluitslag of korwe.
- Haarverlies.
- Voel onwel oor die algemeen (malaise), hoë temperatuur (koors).
- Impotensie.
- Hoë vlak van proteïene in jou uriene (gemeet deur 'n toets).
- Lae vlakke van bloedsuiker of natrium, hoë vlak van bloed ureum (alles gemeet deur 'n bloedtoets).
- Raynaud se verskynsel, waar jou hande, voete baie koud en wit kan word as gevolg van lae bloedvloei.
- Veranderinge in bloedwaardes soos 'n laer aantal wit- en rooibloedselle, laer hemoglobien, laer aantal bloedplaatjies.
- Beenmurgonderdrukking.
- Geswelde kliere in die nek, armholte of lies.
- Outo-immuunsiektes.
- Vreemde drome of slaapprobleme.
- Akkumulasie van vloeistof of ander stowwe in die longe (soos gesien op X-trale).
- Inflammasie van jou neus.
- Inflammasie van die longe wat moeilike asemhaling veroorsaak (longontsteking).
- Inflammasie van die wange, tandvleis, tong, lippe, keel.
- Verminderde hoeveelheid uriene.
- Uitslag met 'n "bullseye" patroon (eriteem multiforme).
- Stevens Johnson se sindroom en toksiese epidermale nekrolise (ernstige veltoestande waar jy rooi en afskilfering van jou vel het, blase of rou sere), eksfoliatiewe dermatitis/ eritroderma (ernstige veluitslag met afskilfering van die vel), pemphigus (klein vloeistofgevulde knoppe op die vel).
- Lewer of galblaasprobleme soos laer lewerfunskie, inflammasie van jou lewer, geelsug (vergeling van die vel of oë), hoë vlakke van lewerensieme of bilirubien (gemeet deur 'n bloedtoets).
- Vergroting van die borste in mans (ginekomastie).
- Swelling van jou derm (intestinale angioedeem).

Ander newe-effekte (frekwensie onbekend):
- Oorproduksie van die antidiuretiese hormoon, wat vloeistofretensie veroorsaak, wat swakheid, moegheid of verwarring tot gevolg het.
- 'n Simptoomkompleks is gerapporteer wat sommige of al die volgende kan insluit: koors, inflammasie van die bloedvate (serositis/ vaskulitis), spierpyn (mialgie/ miositis), gewrigspyn (artralgie/ artritis). Veluitslag, fotosensitiwiteit of ander vel manifestasies kan voorkom.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA aanmeld 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 newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van ENALAPRIL BIOTECH te verskaf.

5. Hoe om ENALAPRIL BIOTECH te bewaar
- Bewaar alle medisyne buite bereik van kinders.
- Bewaar teen of benede 25 °C.
- Bewaar in die oorspronklike verpakking tot gebruik, om teen vog te beskerm.
- Moenie in jou badkamer bewaar nie, om die kontak met vog in die omliggende lug te beperk.
- Moenie die tablette neem na die vervaldatum wat op die houer of buitenste karton gedruk is nie.
- Gee alle ongebruikte of vervalde medisyne aan jou apteker terug en moenie hierdie medisyne in dreine of rioolstelsels (via afvalwater of huishoudelike afval) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat ENALAPRIL BIOTECH bevat
Elke ENALAPRIL 5 BIOTECH tablet bevat 5 mg enalaprilmaleaat.
Elke ENALAPRIL 10 BIOTECH tablet bevat 10 mg enalaprilmaleaat.
Elke ENALAPRIL 20 BIOTECH tablet bevat 20 mg enalaprilmaleaat.

Die ander bestandele is:
ENALAPRIL 5 BIOTECH: natriumkroskarmellose, ysteroksied (rooi), laktosemonohidraat, magnesiumstereaat, mieliestysel, voorgegelatineerde stysel en natriumwaterstofkarbonaat.
ENALAPRIL 10 BIOTECH en ENALAPRIL 20 BIOTECH: natriumkroskarmellose, ysteroksied (swart), ysteroksied (rooi), laktosemonohidraat, magnesiumstereaat, mieliestysel, voorgegelatineerde stysel en natriumwaterstofkarbonaat.

Hoe ENALAPRIL BIOTECH lyk en die inhoud van die pak:
ENALAPRIL 5 BIOTECH: Pienk, gevlekte, ronde, plat tablette met afgeronde rante, met "ELP 5" aan die een kant gedruk en 'n breeklyn aan die ander kant.
ENALAPRIL 10 BIOTECH: Pienk-bruin, gevlekte, ronde, plat tablette met afgeronde rante met "ELP 10" op gedruk.
ENALAPRIL 20 BIOTECH: Grys-violet, gevlekte, ronde, plat tablette met afgeronde rante met "ELP 20" op gedruk.
Aluminiumfoelie stulptroke wat 20, 30 en 90 tablette bevat.

Houer van die sertifikaat van registrasie

Biotech Laboratories (Edms.) Bpk.
Grondvloer, Blok K Wes, Central Park
16de Weg 400, Randjespark
Halfweghuis
Midrand 1685
Tel nr.: +27 (0) 11 848 3050

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Registrasienommers
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ENALAPRIL 10 BIOTECH: 37/7.1.3/0331
ENALAPRIL 20 BIOTECH: 37/7.1.3/0332