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 health care 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 inhibitor (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, a medicine used to treat diarrhoea.
  - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
  - Vildagliptin, a medicine used to treat diabetes.
- If you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin 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 health care provider if you are taking any other medicine.

(This includes all 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, breastfeeding and fertility

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 health care provider for advice before taking ENALAPRIL BIOTECH. ENALAPRIL BIOTECH can cause serious harm to your baby.

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.

Fertility: There is no information on how this medicine affects the ability to have children.

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.

It is not always possible to predict to what extent ENALAPRIL BIOTECH may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ENALAPRIL BIOTECH affects them.

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.

ENALAPRIL BIOTECH contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

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, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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 health care provider for advice.

If any of the following happens, stop taking 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 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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 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

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ENALAPRIL 5 BIOTECH: 37/7.1.3/0330

ENALAPRIL 10 BIOTECH: 37/7.1.3/0331

ENALAPRIL 20 BIOTECH: 37/7.1.3/0332

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.