PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ENPRESIL 5 (Tablets)

ENPRESIL 10 (Tablets)

ENPRESIL 20 (Tablets)

Enalapril maleate

ENPRESIL contains sugar (lactose monohydrate).

Each tablet of **ENPRESIL 5** contains 63,875 mg of lactose monohydrate.

Each tablet of **ENPRESIL 10** contains 58,875 mg of lactose monohydrate.

Each tablet of **ENPRESIL 20** contains 117,75 mg of lactose monohydrate.

This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially 'sodium-free'.

Read all of this leaflet carefully before you start taking ENPRESIL.

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.

ENPRESIL 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 **ENPRESIL** is and what it is used for

2. What you need to know before you take **ENPRESIL**

3. How to take **ENPRESIL**

4. Possible side effects

5. How to store **ENPRESIL**

6. Contents of the pack and other information

1. What ENPRESIL is and what it is used for

ENPRESIL is used to treat:

- Hypertension (high blood pressure)
- Heart failure
- Asymptomatic left ventricular dysfunction (heart problems).

2. What you need to know before you take ENPRESIL

Do not take ENPRESIL:

- If you are hypersensitive (allergic) to enalapril maleate or any of the other ingredients of **ENPRESIL**.
- If you have previously been treated with a medication in the same group of medicines as **ENPRESIL** (ACE inhibitors) or with a medication in the group of medicines known as angiotensin receptor blockers and have had allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing.
- If you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why

was not known or it was inherited.

- If you have a serious heart disease called hypertrophic obstructive cardiomyopathy.
- If you have severe kidney dysfunction.
- If you have renal artery stenosis, a kidney disease where the blood supply to your kidney is reduced.
- If you have aortic stenosis (narrowing of the main heart valve leading from the heart).
- If you are also taking potassium sparing diuretics such as spironolactone, triamterene, amiloride.
- If you have a hereditary condition called porphyria.
- If you are also receiving lithium therapy: Administration together with **ENPRESIL** may lead to toxic blood concentrations of lithium.
- If you are pregnant or breastfeeding (See **Pregnancy and breastfeeding**).
- If you are taking aliskiren containing products.
- If you are taking antibiotics belonging to fluoroquinolone family (e.g. Ciprofloxacin, levofloxacin etc).

Warnings and precautions:

Special care should be taken with **ENPRESIL:**

- If you are taking any of the following medicines used to treat high blood pressure (See **Do not take ENPRESIL**):
    - an angiotensin-converting-enzyme (ACE) inhibitor, for example perindopril and lisinopril
    - 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 hypotension occurs (low blood pressure). You should be closely monitored if your doctor adjust your dose of **ENPRESIL.**
- If you have been diagnosed with a heart valve disease or if your heart struggles to pump blood.
- If your kidneys don't work as well as it should, your doctor might be required to reduce or less frequent your dose.
- If you are using a diuretic (water pills) .
- If you have a history of swelling or if you experience swelling of the face, hands, feet, lips, tongue or throat whilst using **ENPRESIL.** You should contact your doctor immediately.
- If you are being treated with dialysis.
- If you experience a persistent cough.
- If you have planned surgery or will be undergoing anaesthesia.
- If you have high blood pressure due to kidney function abnormalities (See **Do not take ENPRESIL**).
- If you had a recent kidney transplant.
- If you have liver abnormalities or liver failure.
- If you have been diagnosed with low white blood cells.
- If you are undergoing LDL apheresis (removal of cholesterol from your blood).

Other medicines and ENPRESIL

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

(This includes complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with **ENPRESIL** with your doctor or pharmacist:

- Fluoroquinolones e.g. Ciprofloxacin, levofloxacin (see **Do not take ENPRESIL** and **Take special care with ENPRESIL**).
- Other antihypertensive medicines (See **Do not take ENPRESIL**).
- Potassium sparing diuretics (avoid the possibility of potassium loss), potassium supplements or potassium containing salt substitutes.
- Lithium salts usually found in psychiatric medications (See **Do not take ENPRESIL**).
- Non-Steroidal Anti-inflammatory medication especially if you have compromised kidney function.
- Certain anaesthetic medicinal products, tricyclic antidepressants and antipsychotics used together with ACE-inhibitors could further reduce blood pressure.
- Sympathomimetics used in together with ACE-inhibitors may reduce the antihypertensive effects.
- Antidiabetic medicines as this may increase the risk of hypoglycaemia (low blood sugar).
- Gold therapy such as sodium aurothiomalate, which can lead to flushing of your face, feeling sick (nausea or vomiting) and low blood pressure.
- Alcohols used together with ACE-inhibitors intensifies the hypotensive effect.

ENPRESIL with food and drink:

ENPRESIL can be taken before, during or after meals.

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 professional for advice before taking this medicine.

Pregnancy:

You must not take **ENPRESIL** if you are pregnant. Safety in pregnancy has not been established. If an ACE-inhibitor is needed a different anti-hypertensive treatment that is safe in pregnancy should be considered.

Breastfeeding:

You must not take **ENPRESIL** if you are breastfeeding.

Driving or using machinery:

Caution is necessary when driving or performing tasks requiring alertness, as some people may feel dizzy or sleepy during treatment with **ENPRESIL**. Do not drive or operate any tools or machines until you know how **ENPRESIL** affects you because your concentration may be affected.

ENPRESIL contains lactose. Patients with the rare hereditary conditions of lactose intolerance should not take **ENPRESIL.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ENPRESIL.**

3. HOW TO TAKE ENPRESIL:

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

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

High blood pressure:

The usual starting dose is 10 to 20 mg once daily. The maintenance dose is usually 20 mg once daily. Your doctor will adjust your dose according to your specific needs.

Heart failure:

The usual starting dose of **ENPRESIL** is 2,5 mg once daily under medical supervision, and your doctor will adjust your dose according to your response. If you have severe heart failure, your treatment with **ENPRESIL** will be started while you are in hospital, where you can be closely monitored by your doctor.

If you are an elderly patient (over 65 years of age) or if you have kidney problems, your doctor will start your treatment with **ENPRESIL** on a lower dose of 2,5 to 5 mg once daily and adjust your dose according to your response and blood pressure.

Take your tablet(s) with a glass of water, with or without food, preferably at the same time each day.

If you take more ENPRESIL 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.

Contact your doctor immediately if you think you have taken more **ENPRESIL** than you should.

If you forget to take ENPRESIL:

If you have missed a dose, take it as soon as you remember. Do not take a double dose of **ENPRESIL** to make up for forgotten individual doses.

If you stop taking ENPRESIL:

DO NOT stop taking **ENPRESIL** without discussing this with your doctor, even if you feel better.

4. POSSIBLE SIDE EFFECTS:

ENPRESIL can have side effects.

Not all side-effects reported for **ENPRESIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking **ENPRESIL** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the arms, legs, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to Enalapril Unicorn. 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:

- Symptoms of a heart attack including chest pain or discomfort, shortness of breath, pain or discomfort in the jaw, neck, back, arm, or shoulder, feeling nauseous, light-headed, or unusually tired
- Changes in the way your heart beats, for example, if you notice it beating faster
- Symptoms of a stroke including trouble walking, speaking and understanding what others are saying, as well as paralysis or numbness of the face, arm or leg, and vision problems
- Difficulty breathing, lung problems with symptoms including fever, cough, shortness of breath, night sweats and weight loss
- Less urine than is normal for you
- Yellowing of the skin and eyes, dark urine and tiredness, which may be symptoms of liver problems.

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

The following side-effects are frequently experienced with the use of **ENPRESIL**:

- Depression, headache, taste alteration
- Blurred vision
- Chest pain, dizziness, low blood pressure, excessive high blood pressure in high risk patients, fainting
- Cough, shortness of breath
- Stomach pain, diarrhoea, nausea
- Lack of energy, tiredness

- A high level of potassium in the blood, kidney disease.

Other less frequent side effects associated with the use of **ENPRESIL** include:

- Lack of red blood cells, autoimmune diseases (a disease in which the body's immune system attacks healthy cells, low white blood cell count, bone marrow depression, low red blood cell count, swollen lymph nodes, low platelets count
- Low blood sugar, low blood sodium levels
- Dream abnormality, confusion, problems falling and staying asleep, nervousness, pins and needles, excess sleepiness, dizziness
- Ringing in ears
- Flushing, sudden drop in blood pressure, reduced blood flow
- Asthma, hoarseness, runny nose, sore throat, nasal congestion, sneezing and itching of the nose
- Eating disorder, constipation, dry mouth, indigestion, stomach irritation, inflammation of the tongue, blockage in your intestine, pancreatic, burning, pain in the stomach, inflammation inside the mouth, vomiting
- Patchy hair loss, sweating, skin lesions, scaling of the skin, blistering of the skin, itching, skin rash
- Muscle cramps
- Swollen male breast tissue, impotence.

Side effects that can occur together includes fever, inflammation of the serous membrane, inflammation of the blood vessels, muscle pain, joint pain, inflammation in the body, high white blood cells count, rash, hypersensitivity to sunlight and other effects on your skin.

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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to

enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of **ENPRESIL**.

5. How to store ENPRESIL

Store at or below 25 ºC.

Store in the original packaging.

Do not take after the expiry date stated on the package.

Return all unused **ENPRESIL** to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ENPRESIL contains

The active substance is ENALAPRIL MALEATE.

The other ingredients are: Maleic Acid, Hypromellose E 464 (HPMC E 5), Croscarmellose Sodium, Sodium Stearyl Fumarate.

ENPRESIL contains sugar (lactose monohydrate).

What ENPRESIL looks like and contents of the pack

ENPRESIL 5: White to off white, round, flat-face beveled edge tablets with “5” embossed on one side and breakline on the other side.

ENPRESIL 10: White to off white, round, flat-face beveled edge tablets with “10” embossed on one side and breakline on the other side.

ENPRESIL 20: White to off white, round, flat-face beveled edge tablets with “20” embossed on one side and breakline on the other side.

ENPRESIL tablets are packed in white opaque, non-toxic, well thermoformable PVC film coated with PVDC on outer side.

Pack sizes:

30 tablets

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Woodstock, Cape Town, 8001

South Africa

Application number(s)

ENPRESIL 5: A 55/7.1.3/0354

ENPRESIL 10: A 55/7.1.3/0355

ENPRESIL 20: A 55/7.1.3/0356

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