PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

Enpresil Co 20/12.5mg Tablets

Enalapril maleate/hydrochlorothiazide

Enpresil Co contains sugar (lactose monohydrate 130,10 mg)

Enpresil Co is sodium-free

Read all of this leaflet carefully before you start taking Enpresil Co

- 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 Co 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 Co is and what it is used for
2. What you need to know before you take Enpresil Co
3. How to take Enpresil Co
4. Possible side effects
5. How to store Enpresil Co
6. Contents of the pack and other information

1. What Enpresil Co is and what it is used for

Enpresil Co contains enalapril maleate and hydrochlorothiazide:

- Enalapril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors) and widens your blood vessels. This makes it easier for your heart to pump blood to all parts of your body.
- Hydrochlorothiazide belongs to a group of medicines known as water tablets (diuretics),

which make your kidneys pass more water and salt as urin

The effect of both of these medicines is to lower your blood pressure. Enpresil Co is used to treat high blood pressure (hypertension).

2. What you need to know before you take Enpresil Co

Do not take Enpresil Co

- if you are allergic to enalapril maleate, hydrochlorothiazide, or any of the other ingredients of this medicine (listed in section 6)
- if you have previously been treated with a medication in the same group of medicines as this medicine (ACE inhibitors) and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. You should not take this medicine if you have had this type of reaction without a known cause, or if you have been diagnosed with hereditary or idiopathic angioedema
- if you have hypertrophic obstructive cardiomyopathy (HOCM), a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.
- if you are allergic to any sulfonamide-derived medicines. (Ask your doctor if you are not sure what sulfonamide-derived medicines are.)
- if you are not passing urine
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are pregnant or breastfeeding
- if you have a condition known as narrowing of the arteries that supply the blood to your kidneys (renal artery stenosis)
- if you have narrowing of the arteries that supply blood to your heart, and from your heart to other parts of the body (aortic stenosis)
- if you are taking water tablets (diuretics) such as spironolactone, eplerenone, triamterene or amiloride, that cause your body to hold potassium

- if you have porphyria
- if you are taking lithium (a medicine used to treat some psychiatric illnesses)
- if you have severe kidney or liver problems
- if you are being treated with sacubitril/valsartan, a medicine for heart failure.

Do not take Enpresil Co if any of the above applies to you. If you are not sure, talk to yo doctor or pharmacist before taking Enpresil Co.

Warnings and precautions

Talk to your doctor or pharmacist before taking Enpresil Co:

- if you think you are (or might become) pregnant. This medicine is not recommended pregnancy, as it may cause serious harm to your baby (see pregnancy section)
- if you have kidney problems, have had a recent kidney transplantation, are a dialy patient, or are taking water tablets (diuretics)
- if you have blood disorders or liver problems
- if you have a heart condition called 'aortic stenosis', 'hypertrophic cardiomyopathy' 'outflow obstruction'
- if you have collagen vascular disease, are taking immunosuppressant therapy (used the treatment of autoimmune disorders such as rheumatoid arthritis or followi transplant surgery)
- if you are taking allopurinol, (used for the treatment of gout), or procainamide, (used treat abnormal heart rhythms).
- If you develop an infection (symptoms may be high temperature or fever), you should your doctor know immediately. Your doctor may take a blood sample from time to time check your white blood cell count
- if you have a history of 'angioedema' while taking other medicines. Signs include itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids
- if you have diabetes and are taking antidiabetic medicines, including insulin to control

your diabetes (you should monitor your blood for low blood glucose levels, especially during the first month of treatment)

- if you are taking potassium supplements, potassium containing salt substitutes, or other medicines that may increase potassium in your blood [e.g., heparin (a medicine used to prevent blood clots), trimethoprim-containing products such as co-trimoxazole [medicines used to treat infections)]
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Enpresil Co.
- tell your doctor if you are taking 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) or a medicine containing a neprilysin inhibitor such as sacubitril (available as fixed-dose combination with valsartan), used in patients with heart failure, and racecadotril, used in patients with acute diarrhoea. You may be at an increased risk for an allergic reaction called angioedema.
- tell your doctor if you are taking either 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 have been told by your doctor that you have an intolerance to some sugars.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g., potassium) in your blood at regular intervals.

See also information under the heading "Do not take Enpresil Co."

If you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking Enpresil Co:

- any surgery or receive anaesthetics (even at the dentist)
- a treatment called LDL apheresis, to remove cholesterol from your blood using a machine
- desensitisation treatment, to reduce the effect of an allergy to bee or wasp stings.

Routine tests

When you first start to take Enpresil Co, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, sodium, magnesium, creatinine and liver enzyme levels.

Tell your doctor if you have or will take an anti-doping test since this medication can produce a positive result.

Children and adolescents

Enpresil Co is not recommended for use in children.

Other medicines and Enpresil Co

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In general, Enpresil Co can be taken with other medicines. For prescribing the correct dose of Enpresil Co, it is especially important for your doctor to know whether you are taking any of the following medicines:

- an angiotensin II-receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Enpresil Co” and “Warnings and precautions”)
- potassium sparing water tablets (diuretics) such as spironolactone, eplerenone,

triamterene or amiloride, potassium supplements, potassium-containing salt substitutes or other medicines that may increase potassium in your blood (e.g., heparin which is a medicine used to prevent blood clots), trimethoprim-containing products such as co-trimoxazole (medicines used to treat infections)). Enpresil Co may increase the levels of potassium in your blood

- water tablets (diuretics) such as thiazides, furosemide, bumetanide
- other medicines that lower blood pressure, such as nitroglycerin, nitrates, and vasodilators
- lithium, used for the treatment of some psychiatric illnesses
- barbiturates (sedatives used for sleeplessness or epilepsy)
- tricyclic antidepressants such as amitriptyline, used for depression, antipsychotics such as phenothiazines, used for severe anxiety
- pain killers such as morphine or anaesthetics, as your blood pressure may become too low
- cholestyramine or colestipol (used to help control cholesterol levels),
- medicines used for, stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
    - including gold therapy which can lead to flushing of your face, nausea, vomiting and low blood pressure, when taken with Enpresil Co, and
    - non-steroidal anti-inflammatory drugs (NSAIDs), for example diclofenac, which may lead to your blood pressure not being controlled and may increase the level of potassium in your blood
- medicines such as ephedrine, used in some cough and cold remedies, or noradrenaline and adrenaline used for low blood pressure, shock, cardiac failure, asthma or allergies. If used with Enpresil Co these medicines may keep your blood pressure high
- ACTH (to test whether your adrenal glands are working properly)
- corticosteroids (used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders)

- allopurinol (used to treat gout)
- ciclosporins (immunosuppressive medicines used for autoimmune disorders)
- medicines for treating cancer
- procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms)
- digitalis (used to treat heart rhythm problems)
- carbenoxalone (used to treat stomach ulcers)
- excessive use of laxatives
- antidiabetic medicines such as insulin. Enpresil Co may cause your blood sugar levels to drop even further if you take it with antidiabetics
- 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"
- a medicine containing a neprilysin inhibitor such as sacubitril (available as a fixed dose combination with valsartan) and racecadotril. 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 Enpresil Co" and "Warnings and precautions".

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Enpresil Co.

Enpresil Co with food, drink and alcohol

Take Enpresil Co with a glass of water.

If you drink alcohol while taking Enpresil Co, it may cause your blood pressure to drop too much, and you may experience dizziness, light-headedness or faintness. You should keep your alcohol intake to a minimum.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist or other health care provider before taking this me

Pregnancy

Your doctor will normally advise you to stop taking Enpresil Co before you become p or as soon as you know you are pregnant and will advise you to take another m instead of Enpresil Co. Enpresil Co is not recommended during pregnancy as it ma serious harm to your baby.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Enpresil C recommended for mothers who are breastfeeding.

Driving and using machinery

The side effects of Enpresil Co include blurred vision, feeling dizzy, feeling dro confused (see Possible side effects). If you experience these side effects, do not drive any tools or machines.

It is not always possible to predict to what extent Enpresil Co may interfere with t activities of a patient, therefore do not engage in the above activities until you are a the measure to which Enpresil Co affects you.

Enpresil Co contains lactose and sodium

Enpresil Co contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Enpresil Co

Taking this medicine

- Take this medicine by mouth.
- Take this medicine exactly as your doctor or pharmacist has told you.
- Your doctor will tell you how long you should be taking Enpresil Co.
- The number of tablets you take each day will depend upon your condition and whether you are taking other medicines.

Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is:

- One tablet each day.
- Your doctor may increase the dose to two tablets each day.
- Do not take more or less than your doctor has prescribed.

If you have the impression that the effect of Enpresil Co is too strong or too weak, tell your doctor or pharmacist.

If you take more Enpresil Co than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The most common signs and symptoms of an overdose are a decrease in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or light-headedness due to a decrease in blood pressure, strong and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

If you forget to take Enpresil Co

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take Enpresil Co at the next regularly scheduled time. Do not take a double dose to make up for the forgotten dose.

If you stop taking Enpresil Co

Do not stop taking Enpresil Co, unless your doctor tells you to do so. If you stop taking Enpresil Co your blood pressure may increase. If your blood pressure becomes too high, it may affect your heart and kidneys.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Enpresil Co can have side effects.

Not all side effects reported for Enpresil Co are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Enpresil Co, please consult your health care provider for advice.

If any of the following happens, stop taking Enpresil Co and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reaction - you may get a rash, short of breath or wheezy and develop swe your hands, mouth, throat, face or eyes
- severe hypersensitivity reaction with high fever, skin rash that looks like targets (er multiforme); severe skin conditions with reddening, scaling and blistering of tl (Stevens Johnson syndrome and toxic epidermal necrolysis)
- Liver failure or hepatitis. This may cause yellowing of your skin (jaundice).

These are all very serious side effects. If you have them, you may have had a serious r to Enpresil Co. 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:

- severe dizziness, light-headedness, especially at the start of treatment or when your dose is increased or when you stand up.

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

Tell your doctor if you notice any of the following:

Other possible side effects

Frequent side effects

- depression
- dizziness, difficulty sleeping, sleep problems, tingling or numbness, headache, decreased libido, fainting (syncope), muscle weakness, sometimes due to low potassium (paresis)
- blurred vision
- angina or chest pain, heart rhythm changes, fast heartbeat, heart attack or stroke (in high risk patients)
- cough, difficulty breathing
- nausea, diarrhoea, being sick, pain around your stomach area (abdomen), changes in taste
- rash, increased sweating
- muscle cramps
- impotence
- feeling tired, weakness, feeling unwell, fever
- increased blood potassium level, increases in serum creatinine, usually detected by a blood test.

Less frequent side effects

- usually detected by a test: decreased number of red blood cells and low haemoglobin (anaemia), changes in blood test values such as a lower number of white and red blood

cells, lower number of blood platelets, autoimmune diseases

- swollen glands in neck, armpit or groin, blood disorders affecting the components of your blood
- a sense of heightened awareness or a shaky feeling (caused by low blood sugar), increases in blood urea, low levels of potassium in the blood, increased levels of cholesterol, increased levels of triglycerides, low levels of calcium in the blood
- feeling nervous, confusion, strange dreams
- feeling sleepy, feeling like you are spinning (vertigo)
- ringing in your ears
- fast or uneven heart beats (palpitations)
- low blood pressure (which may make you feel dizzy or light-headed, especially if you stand up too quickly), low blood flow to your fingers and toes causing redness and pain (Raynaud's phenomenon)
- runny nose, sore throat and hoarseness, difficulty breathing or asthma, accumulation of fluid or other substances in the lungs (as seen on X-rays), inflammation of the nose eosinophilic pneumonia (symptoms including, high temperature and difficulty breathing), shortness of breath
- indigestion, constipation, flatulence, dry mouth, inflammation of the pancreas (pancreatitis), slow movement of food through your intestine (ileus), not feeling like eating properly (anorexia), stomach irritation, dry mouth, burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a peptic ulcer), pain, swelling or ulcers in your mouth, infection or pain and swelling of your tongue, swelling in your intestine (intestinal angioedema). Signs may include stomach pain, feeling sick and vomiting, elevated calcium level in blood
- itching, hives (urticaria), hair loss
- joint pain
- kidney problems such as lower back pain and reduction in the volume of urine you pass, gall bladder problems

- development of breasts in men
- flushing
- increase in blood urea, increased liver enzymes or blood bilirubin, increases in blood sugar, low level of magnesium in the blood (hypomagnesaemia), decreases in blood sodium levels, usually detected by a blood test.

Frequency unknown side effects

- skin cancer
- salivary gland infection
- production of too much antidiuretic hormone (ADH), determined by a blood test
- restlessness
- yellow vision
- inflammation of blood vessels
- muscle spasm
- glucose (sugar) in the urine, determined by a urine test.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist or nurse.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8.Side effects must also be reported 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 Co.

5. How to store Enpresil Co

- Store all medicines out of the sight and reach of children.
- Store at or below 25 °C.
- Store in the original container
- Do not use this medicine after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Enpresil Co contains

- The active substances in Enpresil Co are enalapril maleate and hydrochlorothiazide. Each tablet contains 20 mg enalapril maleate and 12.5 mg hydrochlorothiazide.
- The other ingredients in Enpresil Co are lactose monohydrate, pregelatinized starch, maleic acid, iron oxide yellow (E172), dried maize starch, sodium stearyl fumarate.

What Enpresil Co looks like and contents of the pack

Enpresil Co is available as pale yellow colour, circular, biconvex uncoated tablets with breakline on one side & plain on the other side.

Enpresil Co is available in blisters and bottles, containing 30 tablets.

Holder of Certificate of Registration

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