PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZESTRIL® 5; ZESTRIL® 10; ZESTRIL® 20 (Tablet)

Lisinopril

Contains sugar: mannitol 20,6 mg (ZESTRIL 5); 41,2 mg (ZESTRIL 10); 41,0 mg (ZESTRIL 20)

Read all of this leaflet carefully before you start taking ZESTRIL

- 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.
- ZESTRIL 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 ZESTRIL is and what it is used for

ZESTRIL belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). ZESTRIL works by widening your blood vessels, which helps reduce

your blood pressure and makes it easier for your heart to pump blood to all parts of your body.

ZESTRIL is used for:

- Treatment of high blood pressure (hypertension) that is mild or moderate. It can be used together with other medications to treat your high blood pressure.
- Management of a heart condition called congestive heart failure when your heart does not pump blood around your body as well as it is needed.
- Treatment after you have had a heart attack (myocardial infarction) to prevent heart failure.

2. What you need to know before you take ZESTRIL

Do not take ZESTRIL:

- If you are allergic to lisinopril or any other ingredients of ZESTRIL.
- If you have previously been treated with a medicine in the same group as ZESTRIL (ACE Inhibitors or ARB's) and have had allergic reactions with itching, hives, sudden fall in blood pressure, swelling of the hands, feet or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing or if you or a member of your family have had a similar reaction.
- If you have a heart condition called aortic valve stenosis or hypertrophic obstructive cardiomyopathy.

- If you are pregnant, trying to fall pregnant, or are breast-feeding.
- If you have a severe kidney problem that affects kidney function.
- If you have a condition known as bilateral renal artery stenosis or stenosis in the presence of a single kidney. This is a narrowing of the kidney arteries supplying blood to the kidney/s leading to a reduced blood flow, resulting in impaired kidney function and high blood pressure.
- If you are taking fluoroquinolones (medicines to treat infections) and you have an impaired kidney function.

The safety in children has not been proven.

Warnings and precautions

Should a woman become pregnant while receiving ZESTRIL, the treatment must be stopped promptly and changed to a different medicine. If a woman is contemplating pregnancy, a different class of medicine should be used.

Take special care with ZESTRIL:

Before taking ZESTRIL tell your doctor, pharmacist or other health care professional if you have:

- Any other heart condition, such as congestive heart failure.
- Low blood pressure (hypotension) or experience dizziness or faintness.
- Any problems with your kidneys.
- Allergies, or experienced any severe allergic reaction.
- Diabetes.
- If you are taking any of the following medicines used to treat high blood pressure:
    - 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 you are taking medicines called mTOR inhibitors (for example temsirolimus, everolimus, sirolimus) or medicines containing NEP inhibitors (for example racecadotril) as they may increase the risk of angioedema. Signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.
- If you are taking fluoroquinolones used to treat infections; in particular if you are elderly or have kidney problems; your doctor may check your kidney function at regular intervals. See also information under the heading “Do not take ZESTRIL”.

While you are taking ZESTRIL tell your doctor, pharmacist or other health care professional if you:

- Suffered from any diarrhoea or vomiting, have taken any water tablets (diuretics) or decreased the amount of salt that you eat in your food.
- Experience any swelling of the face, lips, tongue or throat.
- Are undergoing any surgery where an anaesthetic is being used.
- Are undergoing/or will undergo desensitisation treatment for an allergy, for example to insect stings. The desensitisation treatment reduces the effects of the allergy (e.g. bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking ZESTRIL during the desensitisation treatment.

Other medicines and ZESTRIL

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

If you are taking any of the following medicines, tell your doctor, pharmacist or health care professional:

- Diuretics (water tablets) including spironolactone, triamterene or amiloride.
- Other medicines for your high blood pressure (antihypertensives) including an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take ZESTRIL” and “Take special care with ZESTRIL”.
- Medicines for diabetes, including insulin. Your dose of anti-diabetic may need to be changed.
- Non-steroidal anti-inflammatory medicines (NSAIDS), e.g. indomethacin that you may be using for pain and swelling.
- Medicines for mental disorders, such as lithium.
- Potassium tablets or potassium-containing salt substitutes or other medicines which can increase potassium in your body.
- Medicines to treat cancer (such as everolimus) and medicines given to prevent the body from rejecting a transplanted organ, e.g. kidney or liver (such as temsirolimus, sirolimus).

- Racecadotril used to treat diarrhoea
- Tissue plasminogen activator (TPA) that is used to dissolve blood clots that have formed in blood vessels
- Medicines that contain gold.
- Fluoroquinolones (class of medicines used to treat infections e.g. ciprofloxacin, levofloxacin, moxifloxacin)

ZESTRIL with food and drink

Tablets may be taken before, during or after meals.

Pregnancy and breastfeeding

Before taking ZESTRIL, tell your doctor if you are pregnant, trying to fall pregnant or are breast-feeding.

If you are pregnant or breastfeeding please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You must not take ZESTRIL if you are pregnant or breastfeeding. If you are a woman of childbearing age, ensure that you take adequate contraceptive measures.
You must tell your doctor if you think you are (or might become) pregnant. ZESTRIL is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby, if used at this stage.

Driving and using machines

ZESTRIL can cause dizziness or tiredness and you should not perform such tasks that require special attention until you know how your medicine will affect you.

3. How to take ZESTRIL

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

Always take ZESTRIL 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 ZESTRIL is too strong or too weak, talk to your doctor or pharmacist.

- ZESTRIL should be taken at the same time each day.
- You can take your ZESTRIL with or without food.

Remember, the first dose of ZESTRIL may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as dizziness or light-headedness and it may help to lie down. If concerned please consult your doctor as soon as possible.

The usual dose:

The dosage prescribed to you is individualised and may differ from the information contained in this leaflet.

For high blood pressure (hypertension):

The usual recommended starting dose is 10 mg ZESTRIL taken once a day. The maximum dose is 40 mg a day.

For heart failure:

The usual recommended starting dose is 2,5 mg ZESTRIL taken once a day. The maximum dose is 35 mg once a day.

For acute myocardial infarction (heart attack):

After a heart attack: take 5 mg ZESTRIL on day 1 and 2, then 10 mg ZESTRIL once a day.

If you have problems with your kidneys or take water tablets your doctor may reduce the amount of ZESTRIL that has to be taken compared to the normal adult dose.

If you take more ZESTRIL than you should

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

If you forget to take ZESTRIL

Take the next dose as usual.

Do not take a double dose to make up for the forgotten doses.

4. Possible side effects

ZESTRIL can have side effects.

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

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

- If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat.
- If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing.
- If you develop severe itching of the skin (with raised lumps).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZESTRIL. You may need urgent medical attention or hospitalisation. All of these very serious side effects are rare.

Frequent side-effects:

- headache,
- dizziness or light-headedness - especially when standing up quickly,
- diarrhoea,
- cough,
- vomiting,
- ZESTRIL may affect kidney function,

Less frequent side-effects:

- mood changes,
- numbness or tingling in the fingers or toes,
- changes in the way things taste,
- feeling sleepy or difficulty in going to sleep,
- strange dreams,
- rapid heart-beat,
- running nose,
- nausea,
- stomach pain and indigestion,
- skin rash,
- itching,
- impotence,
- tiredness,
- lack of energy,
- too much potassium in the blood,
- an excessive drop in blood pressure may be experienced in patients with coronary heart disease, or those with a narrowing of the aorta, the kidney artery or the heart valves, or those patients with an increase in the thickness of the heart muscle,
- confusion,
- dry mouth,

- hair loss,
- allergic skin reaction,
- psoriasis (skin disease with raised rough scaly areas),
- rapid/severe kidney failure,
- too little sodium in the blood,
- anaemia,
- sinus pain,
- wheezing,
- inflammation of the pancreas,
- severe skin disorders (symptoms of which include redness, blistering and peeling),
- sweating,
- low blood sugar,
- bone marrow depression,
- ZESTRIL may affect the liver, including yellow skin and/or eyes (jaundice), inflammation of the liver and liver failure,
- ZESTRIL may affect the kidneys causing an abnormally low amount of /or no urine to be passed,

Not known (frequency cannot be estimated from available data):

- Serious allergic reaction.

The following side-effects can also occur with ZESTRIL, and they are seen when a blood test is taken:

- Decrease in the number of platelets in the blood.
- Decrease in the amount of white blood cells and volume of red blood cells.
- Decrease in the quantity of oxygen-carrying pigment, haemoglobin, in the blood.
- Increases in the amount of liver enzymes, blood urea, serum creatinine and breakdown products of red blood cell.

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

5. How to store ZESTRIL

Store all medicines out of reach of children.

Keep your tablets stored at room temperature below 25°C.

ZESTRIL should be stored away from light in a dry place.

Do not use after the expiry date stated on the container.

How to dispose of ZESTRIL?

Take all unused or expired medicines to your pharmacist, doctor or other healthcare professional.

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

6. Contents of the pack and other information

What ZESTRIL contains

- The active substance is lisinopril

Each ZESTRIL 5 tablet contains 5 mg lisinopril as the dihydrate

Each ZESTRIL 10 tablet contains 10 mg lisinopril as the dihydrate.

Each ZESTRIL 20 tablet contains 20 mg lisinopril as the dihydrate.

- The other ingredients are mannitol, calcium hydrogen phosphate dihydrate, maize starch, pregelatinised starch, magnesium stearate, red iron oxide.

What ZESTRIL looks like and contents of the pack

ZESTRIL 5 is a pink round tablet with a heart shape plus the number '5' on one side and a break line on the other side.

ZESTRIL 10 is a pink round tablet with a heart shape plus the number '10' and the word 'ZESTRIL' on one side and may have a logo on the other side.

ZESTRIL 20 is a pink round tablet with a heart shape, the number '20' and the word ‘ZESTRIL’ on one side

ZESTRIL tablets are stored in cartons containing 30 tablets in blister strips.

Holder of Certificate of Registration

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