PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZOFARIL 7,5 mg film coated tablets

ZOFARIL 30 mg film coated tablets

Zofenopril calcium

Contains sugar: ZOFARIL 7,5 mg contains 17,4 mg lactose monohydrate and ZOFARIL 30 mg contains 69,4 mg lactose monohydrate per film coated tablet

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

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

ZOFARIL film coated tablets contain 7,5 mg or 30 mg zofenopril calcium, which belongs to a group of blood pressure-lowering medicines called angiotensin-converting enzyme (ACE) inhibitors.

ZOFARIL is used to treat the following conditions:

- High blood pressure (hypertension).
- Heart attack (acute myocardial infarction) in people who may or may not show signs and symptoms of heart failure, and who have not received treatment that helps dissolve blood clots (thrombolytic therapy).

2. What you need to know before you take ZOFARIL

Do not take ZOFARIL:

- if you are hypersensitive (allergic) to zofenopril calcium or any of the other ingredients of ZOFARIL (see section 6)
- if you have had any previous allergic reaction to any other ACE inhibitor such as captopril or enalapril
- if you have a history of severe swelling and itching around the face, nose and throat (angioedema) associated with previous ACE inhibitor therapy, or if you suffer from hereditary/idiopathic angioedema (rapid swelling of the skin, tissues, digestive tract and other organs)
- if you have taken or are currently taking sacubitril/valsartan (a medicine used to treat a type of long-term (chronic) heart failure in adults) as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased
- if you have heart conditions called hypertrophic obstructive cardiomyopathy (abnormally thick heart muscle that can cause shortness of breath, chest pain or abnormal heart rhythms) or aortic stenosis (narrowing of the valve in the large blood vessel of the heart that can cause shortness of breath, chest pain and tiredness)
- if you suffer from severe kidney problem
- if you suffer from severe liver problems
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you are a woman of child-bearing age, unless if you are using effective contraception
- if you suffer from narrowing of the arteries to the kidneys

- if you have high blood sugar (diabetes) or impaired kidney function and are treated with aliskiren (blood pressure-lowering medicine)
- simultaneous administration of ZOFARIL with lithium may lead to toxic blood concentrations of lithium
- if you are currently taking water tablets such as spironolactone, triamterene, amiloride (used to treat blood pressure)
- if you have a condition called porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin)
- if you have kidney problems or are elderly you should not take a fluoroquinolone antibiotic (used to treat bacterial infections) such as moxifloxacin or levofloxacin while taking ZOFARIL.

Warnings and precautions

Take special care with ZOFARIL:

- if you have high blood pressure and liver or kidney problems
- if you have high blood pressure that is caused by a kidney problem or by narrowing of the artery leading to the kidney (renovascular hypertension)
- if you have recently had a kidney transplant
- if you are undergoing dialysis
- if you are on LDL apheresis (a procedure similar to kidney dialysis that clears your blood of harmful cholesterol)
- if you have abnormally high levels of the hormone aldosterone in your blood (primary aldosteronism)
- if you have a narrowing of the heart valve (aortic stenosis) or thickening of the heart walls (hypertrophic cardiomyopathy)
- if you suffer or have suffered from psoriasis (skin disease characterised by scaly pink patches)
- if you are receiving desensitisation treatment (‘allergy injections’) for insect stings
- if you are elderly or have kidney problems you should not take a fluoroquinolone antibiotic (used to treat bacterial infections) such as moxifloxacin or levofloxacin while taking ZOFARIL

as it may cause or aggravate kidney problems.

- 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, etc.) in particular if you have diabetes-related kidney problems
  - aliskiren.

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 Do not take ZOFARIL.

Your blood pressure may get too low with ZOFARIL, especially after the first dose (this is more likely if you are also taking diuretics, are dehydrated or on a low-salt diet). If this happens, tell your doctor immediately and then lie down on your back.

If you are having an operation, tell your anaesthetist that you are taking ZOFARIL before being anaesthetised. This will help him/her to control your blood pressure and heart rate during the procedure.

In addition if you suffer from a heart attack (acute myocardial infarction) and you:

- have low blood pressure (< 100 mmHg) or are in a state of circulatory shock (as a result of your heart problem) – ZOFARIL is not recommended for you
- are over 75 years of age – ZOFARIL should be used with special care.

You must tell your doctor if you think you are (or might become) pregnant. ZOFARIL is not recommended in early pregnancy, and must not be taken if you are pregnant, as it may cause serious harm to your baby (see Pregnancy and breastfeeding).

Children and adolescents

Do not give ZOFARIL to children under the age of 18 years as safety and efficacy have not been established.

Other medicines and ZOFARIL:

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

Tell your doctor if you are taking, have recently taken or might take any other medicines, e.g.:

- sacubitril/valsartan (a combination product used to treat high blood pressure
- sirolimus (used to prevent organ rejection after a kidney transplant)
- temsirolimus (used to treat a type of cancer that begins in the kidney)
- everolimus (used to prevent organ rejection after a transplant)
- medicines that increase blood potassium levels (potassium-sparing diuretics, such as spironolactone, triamterene, amiloride or potassium supplements), potassium-containing salt substitutes
- trimethoprim/sulfamethoxazole (an antibiotic used to treat a variety of bacterial infections)
- fluoroquinolone antibiotics (used to treat bacterial infections) such as moxifloxacin or levofloxacin
- lithium (used to treat mood disorders)
- anaesthetics
- narcotics (such as morphine)
- antipsychotics (used to treat schizophrenia and similar illnesses)
- antidepressants of the tricyclic type, e.g. amitriptyline and clomipramine
- barbiturates (used to treat anxiety, insomnia, and seizure disorders)
- other high blood pressure medicines and vasodilators (including beta-blockers, alpha-blockers and diuretics such as hydrochlorothiazide, furosemide, torasemide)
- angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings Do not take ZOFARIL and Warnings and precautions)
- nitroglycerin and other nitrates used for chest pain (angina)
- antacids including cimetidine (used to treat heartburn and stomach ulcers)
- ciclosporin (used after organ transplants) and other immunosuppressants (medicines that suppress your body’s defence)

- heparin (used to thin your blood and prevent blood clots from forming)
- allopurinol (used to treat gout)
- insulin or oral anti-diabetic medicines such as vildagliptin (used to treat high sugar levels)
- cytostatics (used to treat cancer or diseases which affect the body's defence system)
- corticosteroids (powerful anti-inflammatory medicines)
- procainamide (used to control an irregular heart beat)
- nonsteroidal anti-inflammatory medicines (NSAIDs, such as aspirin or ibuprofen)
- sympathomimetics (medicines that act on the nervous system, including some used to treat asthma or hay fever, and pressor amines, e.g. adrenaline)
- racecadotril (used to treat diarrhoea).

ZOFARIL with food, drink and alcohol:

ZOFARIL can be taken with food or on an empty stomach, but the tablet is best taken with water. Alcohol increases the hypotensive (lowering of blood pressure) effect of ZOFARIL; ask your doctor for further advice on drinking alcohol whilst on ZOFARIL.

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 health care provider for advice before taking ZOFARIL.

Pregnancy:

You should not take ZOFARIL if you are pregnant.

You should use contraception while taking ZOFARIL.

If you become pregnant while taking ZOFARIL tell your doctor immediately. If you are planning to have a baby tell you docter, he/she will switch your medicine to a suitable alternative.

Breastfeeding:

You should not breastfeed your baby if you take ZOFARIL.

Driving and using machines:

ZOFARIL may cause dizziness or tiredness. If this happens to you, do not drive a vehicle or operate machinery.

ZOFARIL contains lactose monohydrate:

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

3. How to take ZOFARIL

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

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

Treatment of high blood pressure (hypertension):

The normal starting dose of ZOFARIL is 15 mg, once a day. Your doctor will gradually adjust the dosage (usually at four week intervals) to find the dose that suits you best. Long-term antihypertensive effects are usually obtained with 30 mg of ZOFARIL, once a day. The maximum dose is 60 mg per day, taken in a single or two divided doses.

If you are dehydrated, have a salt deficiency or are taking diuretics (water pills), it may be necessary to start your treatment with 7,5 mg of ZOFARIL.

Liver or kidney problems:

If you have mild to moderate liver impairment or moderate to severe kidney impairment, your doctor will start your treatment with half the therapeutic dose of ZOFARIL (15 mg). If you are receiving dialysis, one-quarter of the usual therapeutic dose (7,5 mg) is needed at the start of your treatment.

Treatment of heart attack (acute myocardial infarction):

ZOFARIL treatment should begin within the first 24 hours after the onset of symptoms.

You will receive ZOFARIL tablets twice a day in the morning and evening, as follows:

- 7,5 mg twice a day, on the first and second day of treatment.
- 15 mg twice a day, on the third and fourth day of treatment.
- From the fifth day onwards, the dose should be increased to 30 mg, twice a day.
- Your doctor may adjust your dose or the maximum dose you receive on the basis of your blood pressure measurements.
- Treatment will then be continued for a further six weeks, or longer, if symptoms of heart failure persist.

Your doctor will tell you how long your treatment with ZOFARIL will last. Do not stop treatment early.

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

If you take more ZOFARIL than you should:

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

Always take the labelled medicine package with you, whether there are any ZOFARIL tablets left or not.

The most frequent symptoms and signs of an overdose are low blood pressure with fainting (hypotension), very slow heart beat (bradycardia), changes in blood chemicals (electrolytes) and kidney dysfunction.

If you forget to take ZOFARIL:

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make

up for forgotten individual doses.

If you stop taking ZOFARIL:

Do not stop taking ZOFARIL unless your doctor tells you to. Should you need to stop taking ZOFARIL, your doctor will decide which is the best method for you. Always consult your doctor before stopping ZOFARIL treatment, whether you are taking it for high blood pressure or following a heart attack.

4. Possible side effects

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- fatigue (tiredness)
- nausea (feeling sick) and/or vomiting (being sick)
- dizziness
- headache

- cough.

Less frequent side effects:

- general weakness
- muscle cramps
- skin rash.

In addition to the side effects reported with ZOFARIL, the following have generally been reported with ACE inhibitors:

- Severe low blood pressure at the start of treatment or when the dosage is increased, with dizziness, impaired vision, fainting (syncope).
- Increased or irregular heartbeat, palpitations and chest pain (heart attack or angina pectoris).
- Impaired consciousness, sudden dizziness, suddenly impaired vision or weakness and/or loss of sense of touch on one side of the body (transient ischaemic attack or stroke).
- Peripheral oedema (accumulation of water in the limbs), low blood pressure on standing, chest pain, muscle aches and/or cramps.
- Reduced kidney function, changes in the amount of daily urine, presence of proteins in the urine (proteinuria), impotence.
- Stomach pain, diarrhoea, constipation, dry mouth.
- Allergic reactions like skin rash, hives (urticaria), itching, peeling, redness, loosening and blistering of the skin (toxic epidermal necrolysis), worsening of psoriasis (a skin disease characterised by scaly pink patches), hair loss (alopecia).
- Increased sweating and flushing.
- Mood changes, depression, sleep disorders, altered skin sensations such as burning, prickling, or tingling (paraesthesia), disorders of balance, confusion, ringing in the ears (tinnitus), taste disturbances, blurred vision.
- Difficulty in breathing, narrowing of the airways in the lung (bronchospasm), sinusitis, runny or

stuffy nose (rhinitis), inflammation of the tongue (glossitis), bronchitis.

- Yellowing of the skin (jaundice), inflammation of the liver or pancreas (hepatitis, pancreatitis), bowel obstruction (ileus).
- Changes in blood tests, such as red blood cell, white blood cell or platelet count or a reduction in all kinds of blood cells (pancytopenia).

  Contact your doctor if you find that you bruise easily or develop an unexplained sore throat or fever.
- Increased blood levels of liver enzymes (transaminases) and bilirubin, increased blood urea and creatinine.
- Anaemia due to rupture of red blood cells (haemolytic anaemia), which may occur if you suffer from G6PD (glucose 6-phosphate dehydrogenase) deficiency.

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. 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 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 ZOFARIL.

5. How to store ZOFARIL

- Store at or below 25 °C.
- Keep blister strip in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZOFARIL contains:

ZOFARIL 7,5 mg: Each film coated tablet contains 7,5 mg zofenopril calcium.

ZOFARIL 30 mg: Each film coated tablet contains 30 mg zofenopril calcium.

Other ingredients are:

Tablet core:

Croscarmellose sodium

Lactose monohydrate

Magnesium stearate

Microcrystalline cellulose

Silica, colloidal anhydrous.

Tablet coating: Opadry® Y-1-7000:

Hypromellose

Macrogol 400

Macrogol 6 000

Titanium dioxide (E171).

What ZOFARIL looks like and contents of the pack:

ZOFARIL 7,5 mg: White, round, film coated tablets with convex faces.

ZOFARIL 30 mg: White, oblong, film coated tablets with break marks on both sides. The tablet can be divided into equal doses.

Transparent PVC/PVDC/silver aluminium blister strips packed into a cardboard carton.

Pack sizes: ZOFARIL 7,5 mg: 12 tablets, and ZOFARIL 30 mg: 28 tablets.

Holder of Certificate of Registration:

LeBasi Pharmaceuticals (Pty) Ltd

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This leaflet was last revised in

Date of registration: 24 January 2023

Registration numbers

ZOFARIL 7,5 mg: 55/7.1/0016.014

ZOFARIL 30 mg: 55/7.1/0017.015