Date: March 2023

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ZAARIO 50 (50 mg, film coated tablets)

ZAARIO 100 (100 mg, film coated tablets)

ZAARIO 50: Each tablet contains 50 mg losartan potassium.

Contains sugar: lactose monohydrate 25 mg/ tablet

ZAARIO 100: Each tablet contains 100 mg losartan potassium.

Contains sugar: lactose monohydrate 50 mg/ tablet

Read all of this leaflet carefully before you start taking ZAARIO

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

1. What ZAARIO is and what it is used for

- The treatment of high blood pressure.
- To protect the kidneys in type 2 diabetic patients with high blood pressure, and with laboratory evidence of proteinuria (a condition in which urine contains an abnormal amount of protein).

2. What you need to know before you take ZAARIO

Do not take ZAARIO:

- If you are hypersensitive (allergic) to losartan potassium or any of the other ingredients of ZAARIO (see section 6).
- If you are pregnant or breastfeeding your baby (see section 2).
- If you have had angioedema (swelling of your face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an angiotensin-converting enzyme inhibitor (ACE inhibitor) or an angiotensin receptor blocker, such as ZAARIO.
- If you have hypertrophic obstructive cardiomyopathy, a serious heart disorder where the muscles of the heart are thickened, interfering with normal blood flow.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of your heart) and the aorta (the main artery leading away from your heart).
- If you have severe kidney disease.
- If you have moderate or severe renal impairment (your kidneys are not functioning normally) and are also taking a fluoroquinolone (a class of antibiotic used to combats a bacterial infection) together with an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as ZAARIO) (see section 2).
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney.
- If you have severe liver problems such as problems with the drainage of the bile from the liver and gall bladder, or any other severe liver disease.
- If you are taking diuretics (water tablets) such as spironolactone, triamterene or amiloride, that cause your body to retain potassium.
- If you have a condition called porphyria (a metabolic disorder).
- If you are taking lithium (used to treat some mood disorders).
- If you are using products containing renin inhibitors such as aliskiren (used to treat high blood pressure).

Warnings and precautions

Take special care with ZAARIO:

- if you have or have had any medical problems, and any allergies
- If you have had a history of angioedema (a severe allergic reaction causing swelling of your face, lips, throat, and/or tongue).
- If you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body.
- If you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body.
- If you have any heart problems or kidney conditions.
- Acute kidney failure (a serious condition resulting in your kidneys losing their function) may be caused by the simultaneous use of fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as ZAARIO) (see section 2).
- Your doctor will assess your kidney function prior to starting simultaneous treatment with such medicines and will monitor your kidney function during treatment with fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an ACE inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as ZAARIO) (see section 2).
- Low blood pressure (symptomatic hypotension) is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea, or vomiting.
- If you have problems with your liver; your doctor or healthcare professional will determine the correct dose for you.
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- If you have elevated potassium levels in your blood. Potassium-sparing diuretics should be avoided.
- If you are an elderly patient.
- If you suffer from cerebrovascular disease (caused by a reduced blood circulation in the brain).
- if you have porphyria

Children and adolescents

Children should not take ZAARIO.

Other medicines and ZAARIO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Any other medicines that lower blood pressure. Blood pressure may also be lowered by one of the following medicines or class of medicines: tricyclic antidepressants, antipsychotics, baclofen, amifostine.
- Fluoroquinolones (a class of antibiotic that combats a bacterial infection) (see section 2).
- An angiotensin-converting enzyme (ACE) inhibitor (a class heart medication) (see section 2)
- A renin-angiotensin receptor blocker (a class of heart medication) (see section 2)
- Potassium-sparing diuretics (water retention medication), potassium-containing medication or potassium supplements such as, certain diuretics: amiloride, triamterene, spironolactone or heparin.
- Medicine containing lithium, used to treat some types of mood disorders.
- Nonsteroidal anti-inflammatory medicines (NSAIDs), especially indomethacin.
- Fluconazole, used to treat certain yeast and fungal infections.
- Rifampicin, used to treat tuberculosis (TB).
- Fluvastatin, used for lowering high cholesterol in certain patients.

ZAARIO with food and drink

ZAARIO may be administered with or without food.

Pregnancy and breastfeeding and fertility

DO NOT take ZAARIO if you are pregnant, suspect that you are pregnant, or are planning to become pregnant.

DO NOT take ZAARIO if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ZAARIO.

Driving and using machines

Do not drive, operate machinery, or do anything else that requires your attention until you know how ZAARIO will affect you.

ZAARIO contains a sugar called lactose monohydrate.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take ZAARIO.

3. How to take ZAARIO

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

Always take ZAARIO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

For convenience and to help you remember, try to take ZAARIO at the same time each day.

For the treatment of high blood pressure:

The recommended starting dose of ZAARIO is 50 mg per day.

The dose may be increased to 100 mg once daily.

The expected blood pressure lowering effect should be reached 3 to 6 weeks after beginning treatment.

To protect the kidneys in type 2 diabetic patients with high blood pressure:

The recommended starting dose of ZAARIO is 50 mg per day. The dose may be increased to 100 mg taken once daily.

Your doctor will determine the correct dose for your condition.

For convenience and to help you remember, try to take ZAARIO at the same time each day.

Losartan tablets should be swallowed whole with a glass of water.

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

If you take more ZAARIO than you should:

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

Take this leaflet and the rest of the remaining ZAARIO with you so the doctor will know what you have taken.

Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take ZAARIO:

If you have missed your 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 ZAARIO at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

ZAARIO can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to ZAARIO. 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:

Side effects occurring frequently

- Your heart beats faster than normally, you can feel your heartbeat, pain in your chest.
- You get an infection in your airways.
- You feel unusually tired or weak (asthenia).
- Swelling of your body (oedema).
- Low blood sugar (hypoglycaemia), which may include

- Symptoms of hunger, nausea, fatigue, drowsiness, light-headedness, dizziness, confusion, nervousness, sweating and chills.
- There is a problem with the way your kidneys work.

Side effects occurring less frequently

- You frequently get infections due to a lack of white blood cells.
- Angina (chest pain).
- Stroke (blurred vision, loss difficulty speaking, muscle weakness, loss of movement in one side of your body).
- Shortness of breath.
- Liver disease with nausea, vomiting, fever, yellowing of the skin and whites of the eyes (hepatitis).
- Pins and needles sensation (paraethesia).

Side effects occurring with unknown frequency

- You feel tired and look pale, because of a decreased number of red blood cells.
- You bleed or bruise more easily than normal due to a decreased number of platelets in your blood.
- Migraine (throbbing headache), loss of your sense of smell.
- Your blood vessels get inflamed.
- Problems with the way your liver works.
- Muscle tenderness or weakness (myalgia), painful, swollen joints (arthralgia).
- Experience a ringing or buzzing like noise (tinnitus).

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently

- Headache, dizziness, a spinning feeling in your head.
- Stuffy nose, inflamed sinuses, cough, sore throat.
- Problems sleeping.
- Stomach pain, indigestion, diarrhoea, nausea (feeling sick).
- Pain in your back, muscle cramps.

- Elevated levels of potassium in your blood, elevated liver enzymes.

Side effects occurring less frequently

- Feeling dizzy when you get up from a sitting or lying position.
- Feeling tired, pain in your legs.
- Hives.
- Problems with your airways.
- Vomiting (being sick).
- Severe constipation.

Side effects occurring with unknown frequency

- Reddening, photosensitivity (skin is sensitive to sunlight).
- Unable to get or maintain an erection (male patients).
- Elevated levels of sodium in your blood.
- Generally feeling unwell.
- Depression.
- Inflammation of your pancreas (pain of your stomach area radiating to your back).
- Taste alteration

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 ZAARIO.

Reporting can also be done directly to Unicorn Pharmaceuticals (Pty) Ltd at:

vigilance@unicornpharma.co.za

5. How to store ZAARIO

- Store at or below 25 °C.

- Protect from moisture.
- Keep the blister strips in the 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 ZAARIO contains

ZAARIO 50: Each tablet contains 50 mg losartan potassium.

Contains sugar: lactose monohydrate 25 mg/ tablet

ZAARIO 100: Each tablet contains 100 mg losartan potassium.

Contains sugar: lactose monohydrate 50 mg/ tablet

The other ingredients are hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch and titanium dioxide.

What ZAARIO looks like and contents of the pack

ZAARIO 50: White to off-white, oval shaped, film coated tablets, scored on one side, debossed with ‘J’ on scored side and ‘50’ on the other side.

ZAARIO 100: White to off-white, capsule shaped, film coated tablets, debossed with ‘J’ on one side and ‘100’ on the other side.

ZAARIO 50: White opaque PVC/PE/PVdC silver aluminium blisters, containing 10 tablets per blister, in an outer cardboard carton. 30 tablets per outer carton pack.

ZAARIO 100: White opaque PVC/PE/PVdC silver aluminium blisters, containing 10 tablets per blister, in an outer cardboard

carton. 30 tablets per outer carton pack.

Holder of Certificate of Registration

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