PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

ZARTAN 12,5 mg film coated tablets

ZARTAN 25 mg film coated tablets

ZARTAN 50 mg film coated tablets

ZARTAN 100 mg film coated tablets

Losartan potassium

ZARTAN is sugar-free

Read all of this leaflet carefully before you start taking ZARTAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZARTAN 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 ZARTAN is and what it is used for

Losartan, the active ingredient of ZARTAN, belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax, which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

ZARTAN has been prescribed to you by your doctor or healthcare provider:

- because you have a condition known as hypertension, “high blood” or high blood pressure
- to protect the kidneys in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria(a condition in which urine contains an abnormal amount of protein).

2. What you need to know before you take ZARTAN

Do not take ZARTAN:

- if you are hypersensitive (allergic) to losartan potassium, or to any of the ingredients of ZARTAN (see section 6)

- if you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with ZARTAN, contact your doctor to re-evaluate your treatment
- if you or your family have a history of serious allergic reaction which includes swelling of the face or throat
- if you have abnormally thickened heart muscles
- if you have severe kidney or liver disease
- if you only have one kidney
- if you have a heart condition
- if you are taking other medicines which retain potassium, such as spironolactone, triamterene or amiloride (see Other medicines and ZARTAN)
- if you suffer from porphyria (a rare blood disorder)
- if you are taking lithium medicines (see Other medicines and ZARTAN)
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you are taking high blood pressure medicines which are in the renin inhibitors or aliskiren-containing group (see Take special care with ZARTAN).

The safety and efficacy of ZARTAN in children has not been established.

Warnings and precautions

Take special care with ZARTAN:

- if you fall pregnant while taking ZARTAN, you should stop taking ZARTAN immediately and inform your doctor as soon as possible (see Do not take ZARTAN and Pregnancy and breastfeeding)
- if you are currently on any fluoroquinolones, such as ciprofloxacin or levofloxacin, as the concomitant use of fluoroquinolone and AngiotensinReceptor Blockers (ARBs), such as ZARTAN, may cause acute kidney injury, contact your doctor to re-evaluate your treatment
- if you are currently being treated for hypertension with other medicines used to lower blood pressure including aliskiren, as your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals
- if you have recently suffered from excessive vomiting or diarrhoea
- if you have liver or kidney disease
- if you are taking high-dose diuretics (water tablets)
- if you are an elderly patient or if you have problems with your kidneys, the potassium levels in your body should be carefully monitored
- if you have problems with your liver.

Other medicines and ZARTAN

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

Combinations containing any of the following medications, depending on the amount present, may also interact with ZARTAN tablets:

- Fluoroquinolones (type of antibiotic), such as ciprofloxacin or levofloxacin, may lead to acute kidney injury, contact your doctor to re-evaluate your treatment
- anti-inflammatory medicines, NSAIDs, especially indomethacin
- sympathomimetic medicines (which include some of the active ingredients in cold and flu preparations, some heart medicines, medicines used to treat glaucoma), as concurrent use with sympathomimetic medicines may reduce the blood pressure lowering effects of ZARTAN
- potassium-sparing diuretics (water tablets), potassium containing medicine, potassium supplements, medicines which retain potassium (amiloride, triamterene, spironolactone) or increases potassium levels (heparin)
- lithium (to treat depression).

ZARTAN with food and drink

ZARTAN can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The use of ZARTAN while you are pregnant or breast feeding is contraindicated (see Do not take ZARTAN).

Driving and using machines

Dizziness or drowsiness may occasionally occur when taking antihypertensive therapy including ZARTAN, in particular at the start of treatment or when the dose is increased.

It is not always possible to predict to what extent ZARTAN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZARTAN affects them.

ZARTAN contains mannitol

ZARTAN contains mannitol and may have a laxative effect.

3. How to take ZARTAN

Do not share medicines prescribed for you with any other person. Always take ZARTAN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adult patients with high blood pressure:

The usual starting dose of ZARTAN is 50 mg per day to control blood pressure over the 24-hour period.

The dose may be increased to 100 mg once daily.

Adult patients with high blood pressure and Type 2 diabetes:

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on your blood pressure response.

Dosage in special patient groups:

A starting dose of 25 mg once daily may be used in the elderly patient over 75 years, and for patients with renal impairment.

A reduced dose should also be considered for patients with hepatic impairment.

Children:

Safety and efficacy in children has not been established.

Your doctor will tell you how long your treatment with ZARTAN will last. Do not stop treatment early because your high blood pressure may return.
If you have the impression that the effect of ZARTAN is too strong or too weak, tell your doctor or pharmacist.

If you take more ZARTAN 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.

Symptoms of overdose may include:

- low blood pressure and fast or irregular heart rate.

If you forget to take ZARTAN

If you forget to take ZARTAN, take as soon as you remember on the same day.

If you do not take a tablet that same day, take your normal dose the next day.

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

If you stop taking ZARTAN

Your blood pressure may gradually rise again if treatment is stopped, and no medicine is taken for high blood pressure.

4. Possible side effects

ZARTAN can have side effects.

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

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

- swelling of the 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 ZARTAN. 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:

- heart pounding, fast heartbeat, chest pain, irregular heartbeat
- difficulty breathing
- pancreas infection (you may experience a few of the following symptoms: abdomen pain in the upper middle or upper left belly, the pain may get worse after eating or when you lay flat on your back)
- liver damage (you may feel very tired, nauseous, pain on your right side just below your ribs, no appetite, fever, yellowing of the skin and eyes, dark urine)
- signs of recurrent infections such as fever, sore throat, sinus infection, ear infection).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- upper airway infection, shortness of breath
- difficulty falling asleep
- headache, head spinning sensation (vertigo)
- cough, stuffy nose, throat infection, sinus infection

- tiredness, swelling from water retention, abnormal physical weakness or lack of energy
- increased potassium level in blood, low blood sugar which will be seen in a blood test (you may feel weak, tired, numbness, nausea, shortness of breath, chest pain, fast or skipped heartbeat)
- decrease sodium level in blood which will be seen in a blood test (you may experience the following symptoms: weakness, tiredness, headache, nausea, vomiting, muscle cramps or spasms, confusion, irritability).
- increased liver enzymes which will be seen in a blood test

Less frequent side effects:

- lack of iron in blood, low platelet count which will be seen in a blood test (you may experience the following symptoms: tiredness, weakness, pale skin, shortness of breath, dizziness, tingling sensation in your legs, tongue swelling, sore mouth, swollen gums)
- orthostatic hypotension (low blood pressure – you may be feeling dizzy when standing upright from a sitting position)
- diarrhoea, heartburn, nausea, stomach pain
- rash, hives
- back pain, muscle cramps, leg pain
- dizziness, migraine, metallic taste in mouth.

The following side effects have been reported but the frequency for them to occur is not known:

- bruising, and slow blood clotting after injury
- inflammation of the blood vessels (symptoms include fever, fatigue, weight loss and muscle and joint pain)
- change in sense of taste, losing sense of taste, vomiting
- severe itching of the skin, sun sensitivity, inflammatory skin disease with redness and scaling that affects nearly the entire body, a rare skin condition that may be characterized by non-cancerous (benign) buildup of white blood cells, which present as lesions or lumps on the skin
- muscle pain, joint pain
- kidney problems (you may experience the following symptoms: nausea, vomiting, less urine than normal, ankles swelling, puffiness around the eyes, unpleasant taste in the mouth, stinky breath, tiredness, shortness of breath, no appetite)
- inability to develop or sustain an erection, impotence
- general feeling of discomfort, illness, or unease with no apparent cause.

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. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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

5. How to store ZARTAN

Store all medicines out of reach of children.

Store ZARTAN in a dry place at or below 25 °C.

Keep the tablets in the original packaging until required for use.

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

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 ZARTAN contains

The active substance is losartan potassium.

The other ingredients are:

Tablet cores:

Croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, povidone.

Film coating:

Hypromellose, propylene glycol, purified talc and titanium dioxide.

What ZARTAN looks like and contents of the pack

ZARTAN 12,5 mg is a white, coated, round biconvex 6 mm tablet embossed "1L" .

ZARTAN 25 mg is a white, coated, round biconvex 8 mm tablet embossed "2L"

ZARTAN 50 mg is a white, coated, round biconvex, scored 10 mm tablet embossed "3L"

ZARTAN 100 mg is a white, coated, oval biconvex 9,2 x 18,3 mm tablet embossed "4L"

ZARTAN 100, 50, 25 and 12,5 mg tablets are packed in PVC/PVDC/Aluminium blister strips of 10 tablets. Three strips will be packed in an outer carton.

Holder of Certificate of Registration

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NAMIBIA

ZARTAN 12,5 mg: NS2 08/7.1.3/0065

ZARTAN 25 mg: NS2 08/7.1.3/0066

ZARTAN 50 mg: NS2 08/7.1.3/0067

ZARTAN 100 mg: NS2 08/7.1.3/0086