APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ZARTAN CO 50/12,5 film coated tablets

ZARTAN CO 100/25 film coated tablets

Losartan potassium and Hydrochlorothiazide

ZARTAN CO tablets contain sugar (lactose monohydrate) in the following quantities: ZARTAN CO 50/12,5 (70,31 mg), ZARTAN CO 100/25 (140,61 mg)

Read all of this leaflet carefully before you start taking ZARTAN CO

- 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 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 ZARTAN CO is and what it is used for

ZARTAN CO is a combination of losartan potassium which belongs to a class of medicines called angiotensin II receptor antagonists, and hydrochlorothiazide which is a diuretic (water tablet). ZARTAN CO keeps blood vessels from narrowing, thereby lowering blood pressure and improving blood flow.

ZARTAN CO is used in the treatment of a condition called hypertension or high blood pressure.

2. What you need to know before you take ZARTAN CO

Do not take ZARTAN CO:

- if you are hypersensitive (allergic) to losartan, hydrochlorothiazide, other sulphonamides (sulfa medicines) or to any of the ingredients of ZARTAN CO (see section 6)
- if you have a history of previous and/or current basal cell carcinoma and/or squamous cell carcinoma of the skin and lip
- if you are unable to pass or produce urine
- if you have a severe kidney disorder

- if you have a severe liver disorder
- if you have a history of angioedema (condition where severe swelling of the skin tissue occurs under the surface layer of the skin), be it either inherited, with unknown cause or as a result of taking medicines used to inhibit the angiotensin-converting enzyme or to block the angiotensin receptor (you must never again be given these medicines)
- if you have hereditary or idiopathic angioedema (swelling attacks happen regularly without an identifiable cause)
- if you have a condition which affects your blood vessels which decrease blood flow to your brain or your heart
- if your heart muscle does not pump blood as well as it should
- if you have narrowing or blockage of the blood vessels to both kidneys or to a single functioning kidney
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- if you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with ZARTAN CO, contact your doctor to re-evaluate your treatment
- if you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart)
- if you are taking medicines used to increase urine production

which causes an increase of potassium levels in your blood (such as spironolactone, triamterene or amiloride)

- if you have a condition called porphyria
- if you have Addison's disease, characterised by low blood pressure, weight loss, weakness and bronze-like spots on the skin
- if you are receiving therapy with lithium (medicine to treat depression)
- if you have been told that you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you have diabetes and you are simultaneously using aliskiren (medication used for treatment of high blood pressure), see Other medicines with ZARTAN CO
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Do not use in children as safety has not been established.

Warnings and precautions

Take special care with ZARTAN CO:

If you are pregnant or become pregnant you should stop taking ZARTAN CO and be changed to a different medicine (see Do not take ZARTAN CO).

Tell your doctor if any of the following applies to you:

- if you have a fluid or electrolyte imbalance due to excessive fluid loss, vomiting or diarrhoea
- if you are taking medicine to treat high blood sugar (diabetes)
- if you have gout (a painful condition where uric acid builds up in the joints)
- if you suffer from high cholesterol
- if you are taking lithium, used for the treatment of some psychiatric illnesses as the combination with ZARTAN CO is contraindicated (see do not take ZARTAN CO)
- if you have a liver or kidney disorder or you have had a kidney transplant
- if you are currently on any fluoroquinolones, such as ciprofloxacin or levofloxacin, as the concomitant use of fluoroquinolone and Renin-angiotensin receptor blockers such as ZARTAN CO may cause acute kidney injury, contact your doctor to re-evaluate your treatment
- if you are being treated with diuretics (water tablets), especially in the elderly
- if your ethnic group is black, as you may be at risk of an increased risk of having an allergic reaction to ZARTAN CO, this medicine may not work as well for you as it does in other ethnic groups
- if you have a lung disorder or asthma

- if you had skin cancer or if you develop an unexpected skin lesion (unusual growth of skin). Treatment with hydrochlorothiazide, as in ZARTAN CO, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melonoma skin cancer). Protect your skin from sun exposure and UV rays while taking ZARTAN CO
- 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 heart disease or heart failure.

Take special care after taking the first dose of ZARTAN CO as you may feel dizzy or light-headed.

Other medicines and ZARTAN CO

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
In particular, tell your doctor if you are taking any of the following medicines which may interact with ZARTAN CO:

- fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin may lead to acute kidney injury. Contact your doctor to re-evaluate your treatment
- other medicines from the same class (angiotensin II receptor antagonists or ACE inhibitors) to lower blood pressure, as effect of ZARTAN CO may be increased

- rifampicin (an antibiotic used to treat certain bacterial infections), as effect of ZARTAN CO may be decreased
- fluconazole (medicine to treat fungal infections), as it may reduce the effect of ZARTAN CO
- potassium-sparing diuretics (water tablets such as spironolactone, potassium supplements and/or potassium-containing salt substitutes, triamterene or amiloride) and certain other diuretics, which could result in high potassium blood levels (common symptoms are vague feeling of discomfort/ feeling bad, palpitations and muscle weakness)
- non-steroidal anti-inflammatory drugs (NSAIDs) to treat pain and arthritis (such as ibuprofen, indomethacin or aspirin), as these may reduce the blood pressure lowering effect of ZARTAN CO and may affect the kidney function or worsen an existing kidney problem
- aliskiren may increase unwanted side effects such as low blood pressure, increased potassium levels in the blood and kidney problems including kidney failure (see Do not take ZARTAN CO)
- alcohol or barbiturates (medicines such as phenobarbitone), as they may increase the effects of ZARTAN CO
- anti-diabetic medicines and insulin, as ZARTAN CO may increase your sugar levels. Your doctor may want to adjust your diabetes medication (see Do not take ZARTAN CO)

- cholestyramine and colestipol (medicine to reduce cholesterol), as these may reduce the effects of ZARTAN CO. These medicines should be taken at least an hour before taking ZARTAN CO
- corticosteroids (used to reduce inflammation, suppress the immune system, and replacement therapy) or glycyrrhizin (found in liquorice), as these may affect the way ZARTAN CO works
- beta$_2$-agonists (used in the treatment of asthma) may increase the way ZARTAN CO works
- norepinephrine (noradrenaline) (used in the treatment of low blood pressure), as ZARTAN CO may affect the way this medicine works
- medicines called sympathomimetics used to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy over the counter). ZARTAN CO may affect the way these medicines work
- muscle relaxants (e.g. tubocurarine), as ZARTAN CO may increase the effects of these medicines
- lithium (medicines for certain types of depression),as ZARTAN CO increases the level of lithium in the blood (see Do not take ZARTAN CO)
- pressor amines, such as adrenaline used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies

- medicines for the treatment of gout (probenecid, sulfinpyrazone and allopurinol), as ZARTAN CO may reduce their effect
- atropine and biperiden (used in the treatment of Parkinson's disease), as ZARTAN CO may increase their effect
- medicines used to treat cancer, as ZARTAN CO may affect the way they work
- salicylates (such as aspirin used for inflammation), as ZARTAN CO may enhance its effect
- methyldopa (used to treat high blood pressure) may increase the risk of anaemia
- ciclosporin (used in organ transplants) may increase the risk of side effects such as gout
- medicines to control heart rhythm (such as digoxin) may increase the risk of side effects such as blood and heart rhythm disorders
- medicines which reduce high cholesterol such as simvastatin or lovastatin
- some laxatives may affect electrolyte balance
- calcium containing medication may require additional blood tests during treatment and dosage adjustment during treatment with ZARTAN CO

- anti-convulsion medicines to treat seizures (such as carbamazepine) may increase the risk of side effects and additional tests to monitor your condition may be required during treatment
- sedatives, narcotics or excessive alcohol may lead to further lowering of blood pressure.

Please also inform your doctor you are taking ZARTAN CO if you will be undergoing a radiographic procedure and will be given iodine contrast media.

ZARTAN CO may interfere with thyroid function tests.

ZARTAN CO with food and drink

ZARTAN CO can be taken with or without food.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before using ZARTAN CO.

Do not take ZARTAN CO if you are pregnant, planning to become pregnant or breastfeeding your baby.

If you become pregnant whilst taking ZARTAN CO, please consult your doctor immediately to change your medication.

You should not use ZARTAN CO while you are pregnant or breastfeeding your baby, as ZARTAN CO may cause harm or death to an unborn baby. If you get pregnant while taking ZARTAN CO, tell your doctor right away.

Tell your doctor if you are breastfeeding or are about to start breastfeeding. ZARTAN CO is contraindicated in mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed.

Women of childbearing age should use contraception.

Driving and using machines

ZARTAN CO may cause dizziness. Please take care before driving or using machinery until you know how ZARTAN CO affects you.
It is not always possible to predict to what extent ZARTAN CO 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 CO affects them.

ZARTAN CO contains lactose

ZARTAN CO contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ZARTAN CO.

ZARTAN CO contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take ZARTAN CO

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

Always use ZARTAN CO exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Take ZARTAN CO every day at the same time, exactly as your doctor has instructed.

It is important to continue taking ZARTAN CO for as long as your doctor prescribes it in order to control your blood pressure.

Adults:

The usual starting and maintenance dose is ZARTAN CO 50/12,5 once daily.

For patients who do not respond adequately, the dosage may be increased to two ZARTAN CO 50/12,5 tablets once daily or one ZARTAN CO 100/25 tablet once daily.

It may take 3 weeks of using ZARTAN CO before your blood pressure is under control. ZARTAN CO may be taken with or without food.

Children:

Not applicable.

Your doctor will tell you how long your treatment with ZARTAN CO will last. Do not stop treatment early because your high blood pressure may return.

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

If you take more ZARTAN CO 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, abnormal or irregular heartbeat, electrolyte changes in your blood, dehydration.

If you forget to take ZARTAN CO

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZARTAN CO

This medicine helps control high blood pressure. You may have to take high blood pressure medicine for the rest of your life. If high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke or kidney disease.

4. Possible side effects

ZARTAN CO can have side effects.

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

If any of the following happens, stop using ZARTAN CO 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 (syncope).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZARTAN 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:

- heart attack (common symptoms are chest pain or discomfort, pressure or tightness in the chest that may spread to your arm, neck, jaw or back)
- increased or fast heart beat (tachycardia), irregular heartbeat, palpitations, chest pain (angina)
- low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness), inflammation of blood vessels, often with skin rash
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- kidney problems (passing less urine than is normal for you), abnormal kidney function including inflammation of the kidneys
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever)
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)

- jaundice (yellow discolouration of the skin and eyes)
- high cholesterol
- electrolyte imbalances, including low blood levels of sodium (hyponatraemia) or low or high levels of potassium (hypokalaemia or hyperkalaemia respectively) in the blood which can cause tiredness, confusion, and fits (convulsion)
- eruption of lesions on the skin or mouth known as erythema multiforme that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring. The lesions can sometimes be painful or itchy
- toxic epidermal necrolysis (TEN) - a life-threatening skin disorder characterised by a blistering and peeling of the skin
- skin and lip cancer (non-melanoma skin cancer), with abnormal growth of skin, bump or sores on the lips that persist for a long period of time
- agranulocytosis (a life-threatening condition that leads to severe infection) results when your body doesn't make enough white blood cells (symptoms include fever, chills, increased heart rate and breathing, sudden drop in blood pressure, muscle weakness and fatigue, pain and/or ulcers in the mouth and throat and bleeding, inflamed gums).

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 respiratory tract infections, cough, nasal congestion, sinus disorders, sore throat
- headaches, dizziness, light-headedness tension on the forehead, sides and on the back of the head, tenderness on scalp, neck and shoulder muscles
- abdominal pain, change in taste perception or complete loss of taste, nausea, diarrhoea, indigestion
- back pain, leg pain, muscle cramps, spasms, weakness or pain
- feeling weak and tired, general chest pain, swelling due to fluid retention
- decrease in blood sugar levels (hypoglycaemia) which could include symptoms such as thirst, increased urination, blurred vision, confusion, anxiety and shakiness
- problems sleeping.

Less frequent side effects:

- blood tests showing a decrease in the number of red blood cells, white blood cells, platelets or the amount of haemoglobin (anaemia), and changes in the results of your blood tests
- anorexia, excess amount of uric acid in the blood, gout, which can cause pain in the joints (hyperuricemia)
- mood and/or sleep disorders, confusion, feeling restless and

depressed, memory loss, anxiety, panic attack, abnormal dreams, sleepiness

- migraine, weakness, nervousness, tingling sensation in hands, feet or lips (feeling of "pins and needles") which may result in lack of coordination and falling, heaviness in the legs, tremor
- blurred vision, worsening eyesight, conjunctivitis (pink eye), burning/stinging in the eye
- vertigo (loss of balance and dizziness), ringing or buzzing in the ears
- discomfort, pain, or scratchiness in the throat, inflammation of your voice box (larynx), shortness of breath, bronchitis, nose bleeds, runny or blocked nose, sneezing, fluid/mucous in the lungs
- hives, rash, inflammation of the skin, rash, redness of the skin, sensitivity to light, purple-colored spots and patches that occur on the skin
- arm pain, joint swelling and pain, knee pain, muscle and/or bone pain, shoulder pain, stiffness, hip pain, muscle weakness, arthritis, muscle injury
- excess urination during the night, urinary infection, sugar in the urine
- problems with sexual performance
- fever.

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

- changes in taste
- flatulence (gas), constipation, wind, stomach pain, stomach spasms, dry mouth, vomiting, dental pain
- flu-like symptoms, general sense of being unwell, often accompanied by fatigue, diffuse pain or lack of interest in activities
- inflammation of a salivary gland
- high blood sugar levels (hyperglycaemia)
- seeing things in yellow
- butterfly-shaped red, scaly rash across the cheeks and bridge of the nose.

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 or nurse. 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 CO.

5. How to store ZARTAN CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Do not remove from the outer carton 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 CO contains

The active ingredients are losartan potassium and hydrochlorothiazide.

Each ZARTAN CO 50/12,5 film coated tablet contains 50 mg losartan potassium and 12,5 mg hydrochlorothiazide.

Each ZARTAN CO 100/25 film coated tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide.

The other ingredients are:

Tablet cores:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch.

Film coating:

Hydroxypropyl cellulose, hypromellose, titanium oxide, yellow iron oxide.

What ZARTAN CO looks like and contents of the pack

ZARTAN CO 50/12,5: Round, yellow film coated tablets with a diameter of 7,5 mm.

ZARTAN CO 100/25: Round, yellow film coated tablets with a diameter of 10,5 mm.

ZARTAN CO 50/12,5 and ZARTAN CO 100/25 are packed into silver aluminium/ clear transparent PVC/PE/PVDC blister packs of 10 tablets.

3 blister strips are packed into a printed outer carton (30 tablets).

Holder of Certificate of Registration

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