

PATIENT INFORMATION LEAFLET

ZARTAN CO

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

ZARTAN CO 50/12,5 film coated tablets

ZARTAN CO 100/25 film coated tablets

Read all of this leaflet carefully before you start taking ZARTAN CO 50/12,5 or 100/25.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

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.

1. WHAT ZARTAN CO CONTAINS:

The active substances 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 hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, titanium oxide, yellow iron oxide.

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)

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2. WHAT ZARTAN CO 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.

3. BEFORE YOU TAKE ZARTAN CO:

Do not take **ZARTAN CO**:

- if you are hypersensitive (allergic) to losartan, hydrochlorothiazide, or to any of the other ingredients of **ZARTAN CO** (see **WHAT ZARTAN CO CONTAINS**)
- if you are hypersensitive (allergic) to other sulphonamides (sulfa medicines)
- 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 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 are unable to pass or produce urine
- if you have a severe kidney disorder
- if you have a severe liver disorder
- 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

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- if you have any heart disorder affecting the way the heart works
- if you have narrowing or blockage of the blood vessels to both kidneys or to a single functioning kidney
- 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
- if you are simultaneously using aliskiren (medication used for treatment of high blood pressure), see **Taking other medicines with ZARTAN CO**
- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

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

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 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

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- 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-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking

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- 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 a lung disorder or asthma
- if you have gout (a painful condition where uric acid builds up in the joints)
- if you have a condition called lupus (systemic lupus erythematosus an autoimmune disease in which the body's immune system mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain, and other organs)
- if you have a liver or kidney disorder or you have had a kidney transplant
- if you suffer from high cholesterol
- 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.

Taking ZARTAN CO with food and drink:

ZARTAN CO can be taken with or without food.

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Pregnancy and breastfeeding:

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **ZARTAN CO**.

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

Women of childbearing age should use contraception.

Driving and using machinery:

ZARTAN CO may cause dizziness. Please take care before driving or using machinery until you know how **ZARTAN CO** affects you.

Important information about some of the ingredients of ZARTAN CO:

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.

Taking other medicines with 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

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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)
- 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**)
- 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
- 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**

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- corticosteroids (used to reduce inflammation, suppress the immune system, and replacement therapy) as these may affect the way **ZARTAN CO** works
- beta₂-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) – **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
- ciclosporin (used in organ transplants) may increase the risk of side effects such as gout
- methyldopa (used to treat high blood pressure) may increase the risk of anaemia

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- 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.

4. HOW TO TAKE ZARTAN CO:

Do not share medicines prescribed for you with any other person. Always take **ZARTAN CO** exactly as your doctor has instructed 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.

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.

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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.

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 an overdose, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

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.

5. 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 taking **ZARTAN CO**, please consult your healthcare provider for advice.

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

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

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.

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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)
- 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)
- chest pain (angina)
- fainting (syncope)
- 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.

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:

- blood tests showing high levels of sodium, dehydration, experiencing fluid loss such as nausea, vomiting, diarrhoea
- problems sleeping

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- headaches, dizziness, light-headedness tension on the forehead, sides and on the back of the head, tenderness on scalp, neck and shoulder muscles
- upper respiratory tract infections, cough, nasal congestion, sinus disorders, sore throat
- abdominal pain, change taste perception or complete loss of taste
- back pain, leg pain, muscle cramps, spasms, weakness or pain
- feeling weak and tired
- blood test showing decreased potassium levels.

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
- a rash of red or purple spots on the skin caused by internal bleeding from small blood vessels
- 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
- 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, seeing things yellow
- vertigo (loss of balance and dizziness), ringing or buzzing in the ears
- hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, blistering or peeling of the skin, hair loss, flushing
- arm pain, joint swelling and pain, knee pain, muscle and/or bone pain, shoulder pain, stiffness, hip pain, muscle weakness

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- excess urination during the night, urinary infection, sugar in the urine
- problems with sexual performance
- fever, dizziness, weakness or restlessness.

Side effects with unknown frequency:

- tiredness or numbness
- stomach pain or discomfort, inflammation of the stomach, bloating, flatulence (gas), constipation, wind, stomach pain, stomach spasms, dry mouth, inflammation of a salivary gland, indigestion, diarrhoea
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

6. STORING AND DISPOSING OF ZARTAN CO:

Store at or below 25 °C.

Protect from light and moisture.

Do not remove from the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after expiry date stated on the carton.

Return all unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).