PATIENT INFORMATION LEAFLET

TESAR CO RANGE

SCHEDULING STATUS:

S3

TESAR CO 40/12,5 mg tablets

TESAR CO 80/12,5 mg tablets

Telmisartan and hydrochlorothiazide

TESAR CO 40/12,5 mg contains sugar alcohol (mannitol 163,85 mg) and sugar (lactose monohydrate 49,84 mg)

TESAR CO 80/12,5 mg contains sugar alcohol (mannitol 327,70 mg) and sugar (lactose monohydrate 49,84 mg)

Essentailly 'sodium free'.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- TESAR 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 TESAR CO is and what it is used for
2. What you need to know before you take TESAR CO
3. How to take TESAR CO
4. Possible side effects
5. How to store TESAR CO
6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET

TESAR CO RANGE

1. What TESAR CO is and what it is used for

TESAR CO is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both substances help to control high blood pressure.

Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase leading to a lowering of your blood pressure.

TESAR CO is used to treat mild to moderate high blood pressure. Your doctor will usually prescribe TESAR CO when your blood pressure has already been controlled after taking both the individual active ingredients of this medicine separately.

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

Do not take TESAR CO:

- if you are hypersensitive (allergic) to telmisartan, hydrochlorothiazide or other sulphonamide-derived medicines, or to any of the ingredients of TESAR CO (see section 6)
- if you have or have ever had skin and lip cancer
- if you suffer from severe kidney disease or you have problems passing water
- if you suffer from severe liver disease such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease
- if your doctor determines that you have low potassium or sodium levels or high calcium levels in your blood that do not get better with treatment
- if you have high levels of uric acid in your blood or are experiencing symptoms of gout

- if you suffer from a severe kidney disorder, narrowing of the blood vessels of both kidneys; or you have only one kidney left, of which the blood vessels are narrowed
- if you suffer from heart disease, including a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM – thickening of the muscle of the heart)
- if after previously taking other angiotensin receptor blockers (ARBs) or angiotensin-converting enzyme (ACE) inhibitors you have experienced swelling of your face, lips, eye lids, mouth, tongue or throat. You must never take these medicines (including TESAR CO) again
- if you have a disease of the heart valves called aortic stenosis in which the opening is narrowed
- if you are currently taking water tablets containing spironolactone, triamterene or amiloride (medicines that increase the rate of urination)
- if you have Addison's disease (a hormonal disorder)
- if you have porphyria (a rare hereditary blood disorder)
- if you are currently taking lithium (used to treat depression or mood disorders). Concomitant administration with TESAR CO may lead to toxic blood concentrations of lithium
- if you are being treated with ACE inhibitors/angiotensin receptor blockers (to treat high blood pressure) together with a fluoroquinolone antibiotic
- if you are being treated with a blood pressure lowering medicine called aliskiren
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with TESAR CO:

Should you become pregnant while taking TESAR CO, stop taking the tablets immediately and contact your doctor. Your doctor may consider switching your medicine to a different treatment (see Do not take TESAR CO).

- if you have high blood pressure caused by kidney disease
- if you have kidney problems, have had a kidney transplant or have a single kidney (see Do not take TESAR CO)
- if your body lacks salt due to a low salt diet, or you have recently lost a lot of body fluids, through taking strong water tablets, or due to vomiting or diarrhoea
- if you are already taking other medicines which lower blood pressure medicines including a medicine containing aliskiren (see Do not take TESAR CO)
- if you have been diagnosed with diabetic neuropathy (a type of nerve damage that can occur in diabetics)
- contact your doctor to re-evaluate your treatment if you are being treated with ACE inhibitors/angiotensin receptor blockers (to treat high blood pressure) together with a fluoroquinolone antibiotic (see Do not take TESAR CO)
- if you have high aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals) (aldosterone is a hormone that helps regulate blood pressure)
- if you have heart problems (irregular heartbeats, angina, chest pain, or had a heart attack or stroke) (see Do not take TESAR CO)
- if you experience fatigue or muscle weakness, as these may be symptoms of a condition called hyperkalaemia
- if you take salt substitutes containing potassium or you have been told by your doctor you have high potassium levels in your blood, as TESAR CO may increase the levels of potassium in your blood and your doctor may need to monitor these levels regularly
- if you have liver problems (see Do not take TESAR CO)
- if you suffer from diabetes (high blood sugar levels)
- if you have been told by your doctor that you have high blood fat or cholesterol levels
- if you have gout. TESAR CO may worsen your gout (see Do not take TESAR CO)

- TESAR CO may lower sodium and magnesium levels in your blood and taking calcium with TESAR CO may raise the calcium levels in your blood (see Other medicines with TESAR CO)
- if you have systemic lupus erythematosus (also known as 'lupus' or 'SLE'), a disease where the body's immune system attacks the body
- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours or weeks of taking TESAR CO. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this
- if you have had skin cancer or if you develop an unexpected skin lesion (unusual growth of skin). Treatment with hydrochlorothiazide as in TESAR 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 TESAR CO
- TESAR CO should not be used if you have or had skin and lip cancer (see Do not take TESAR CO)
- these tablets may be less effective in lowering the blood pressure in black patients
- if you experience symptoms of respiratory toxicity (cough, tightness in chest, and shortness of breath, fever, low blood pressure) when either taking TESAR CO or have experienced these symptoms when taking another medicine containing hydrochlorothiazide, as your doctor will prescribe an alternate medicine
- if you have heart disease and experience an excessive drop in blood pressure
- if you have a history of allergy or bronchial asthma
- if you develop sensitivity of the skin to sun, such as redness, itching, swelling, blistering, your doctor may stop your treatment. You should protect exposed areas of your skin whilst taking TESAR CO

If you experience any of the following symptoms you may have an electrolyte (salt) imbalance caused by the hydrochlorothiazide in TESAR CO, become very thirsty, have a dry mouth, feel unusually tired or weak, experience muscle pains or cramps, feel sick or vomit, or have an unusually fast heartbeat. You should tell you doctor if you experience any of these symptoms.

Children and adolescents

TESAR CO is not recommended in children and adolescents up to 18 years, as safety has not been established.

Other medicines and TESAR CO

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

When taken at the same time as TESAR CO, you may have to stop taking one of the following medicines:

- lithium containing medicines to treat some types of depression (see Do not take TESAR CO)
- fluoroquinolones (antibiotics that are commonly used to treat a variety of illnesses such as respiratory and urinary tract infections) (see Do not take TESAR CO)
- iodinated contrast products (containing iodine that are given to patients to enhance the ability to see blood vessels and organs on medical images such as x-ray and CT images)
- medicines associated with low blood potassium (hypokalaemia), such as other diuretics, (water tablets), laxatives (e.g. castor oil), corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic used to treat infection), and salicylic acid and derivatives (used to treat inflammations)

- medicines that may increase blood potassium levels, such as potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors, cyclosporin (an immunosuppressant medicine) and other medicines such as warfarin and heparin sodium (an anticoagulant)
- aliskiren and similar medicines 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 TESAR CO and Take special care with TESAR CO).

TESAR CO may interact with the following medicines:

- medicines that are affected by changes of the blood potassium level, such as heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. quinidine, disopyramide, amiodarone, sotalol), medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine) and other medicines such as certain antibiotics (e.g. sparfloxacine, pentamidine) or certain medicines to treat allergic reactions (e.g. terfenadine) and medicines that may induce “torsade de pointes” (irregular heartbeat,) such as dolasetron, erythromycin, clarithromycin, halofantrine, moxifloxacin, pimozide, chlorpromazine, ziprasidone and mizolastine
- nonsteroidal anti-inflammatory medicines (NSAIDs), including aspirin, to treat pain, inflammation and arthritis (such as ibuprofen, indomethacin or aspirin), as these may reduce the blood pressure lowering effect of TESAR CO and may affect the kidney function or worsen an existing kidney problem
- alcohol, narcotics or any other medicines that work on the nervous system, as they may increase the effects of TESAR CO
- medicines used to treat high blood sugar (diabetes), including insulin or metformin. Your doctor may want to adjust your diabetes medication
- cholestyramine and colestipol resins (used to treat high cholesterol) affect the way TESAR CO works

- digitalis glycosides, such as digoxin (to treat heart rhythm disorder), as TESAR CO may increase the effects of this medicine
- noradrenaline (used to treat low blood pressure)
- muscle relaxants (e.g. tubocurarine) as TESAR CO may increase the muscle relaxing effects
- medicines for the treatment of gout (probenecid, sulfinpyrazone and allopurinol), as TESAR CO may reduce its effect
- calcium supplements and/or vitamin D supplements
- beta-blockers and diazoxide (medicines used to treat high blood pressure and low blood sugar)
- anti-cholinergic medicines, such as atropine and biperiden (medicines used to treat a variety of disorders, such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, and as an aid to anaesthesia)
- amantadine (used to treat Parkinson's disease) as TESAR CO may increase the risk of unwanted side effects
- cytotoxic medicines (e.g. cyclophosamide, methotrexate) used to treat cancer, as TESAR CO may affect the way they work
- vitamin D may result in increased calcium levels in your blood
- 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
- other medicines used to treat high blood pressure or medicines with blood pressure lowering potential (e.g. baclofen a muscle relaxant, amifostine used to help prevent or lessen some of the side effects of cancer medicine).

TESAR CO with food, drink and alcohol

TESAR CO can be taken with or without food.

TESAR CO taken together with alcohol may cause dizziness or light-headedness.

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 using TESAR CO.

DO NOT take TESAR CO if you are pregnant, plan to become pregnant, or think you may be pregnant. (see Do not take TESAR CO). Contact your doctor or healthcare professional immediately.

DO NOT take TESAR CO whilst breastfeeding your baby (see Do not take TESAR CO).

TESAR CO should not be given to women of childbearing potential unless appropriate contraceptive methods are being used.

Driving and using machines

TESAR CO may occasionally cause fainting, dizziness or drowsiness.

It is not always possible to predict to what extent TESAR 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 TESAR CO affects them.

TESAR CO contains lactose and mannitol

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

TESAR CO contain sodium

TESAR CO contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take TESAR CO

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

Always take TESAR CO exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Two strengths of TESAR CO tablets are available: 40/12,5 mg and 80/12,5 mg. Your doctor will decide which strength is best for you.

Adults:
The usual dose is one TESAR CO tablet daily, with or without food.
Usually, treatment will be continued for at least 4 to 8 weeks, to obtain the maximum effect of lowering your blood pressure in the long term.

Children:
TESAR CO is not recommended for use in children.

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

If you take more TESAR 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:

- a heartbeat which is too fast, too slow or irregular, dizziness, feeling faint, feeling sick or be sick, drowsiness, or experiencing muscle spasms.

If you forget to take TESAR CO

If you forget to take TESAR CO, take the missed dose 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 TESAR CO

Suddenly stopping your treatment may lead to your symptoms getting worse. Do not stop taking TESAR CO unless your doctor tells you to. It is recommended that TESAR CO should be gradually reduced before stopping treatment.

4. Possible side effects

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

The below listed side effects include those that are related to taking TESAR CO as wells as those of the active ingredients telmisartan and hydrochlorothiazide, if taken individually.

If any of the following happens, stop using TESAR 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

- sepsis (blood poisoning - a severe infection with whole-body inflammatory response, rapid swelling of the skin and mucosa (angioedema), blistering and peeling of the top layer of skin (toxic epidermal necrolysis).

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

- low blood pressure or fainting when getting up from a lying or sitting position (orthostatic hypotension/dizziness)
- changes in the way your heart beats (for example if you notice it is beating faster or you experience chest pain)
- 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, urinary infection, sugar in the urine, kidney failure
- difficulty breathing, shortness of breath (interstitial lung disease)
- liver problems resulting in yellowing of the skin and/or eyes (jaundice).

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:

- dizziness
- electrolyte imbalance, dehydration
- nausea.

Less frequent side effects:

- sore throat, chest infection, bladder infection including cystitis

- anaemia (reduced number of red blood cells with symptoms such as feeling generally tired or lethargic, pale skin), low blood platelet count (thrombocytopenia), reduction in blood platelets, which increases risk of bleeding or bruising, decreases in the number (or even lack) of cells in the blood, including low red and white blood cell count
- abnormal breakdown of red blood cells (haemolytic anaemia), inability of the bone marrow to work properly, reduction of white blood cells (leukopenia, agranulocytosis)
- decreased blood potassium (hypokalaemia), sodium (hyponatraemia) and glucose (hypoglycaemia), and increased uric acid levels in the blood, causing gout (hyperuricaemia)
- depression, anxiety, restlessness
- insomnia (sleep disorder), sleep disturbances, pins-and-needles sensation, drowsiness, headache
- abnormal or yellow vision, temporary blurred vision
- vertigo (sensation of spinning)
- diarrhoea, dry mouth, flatulence, stomach pain/discomfort, constipation, indigestion, vomiting, taste disturbance or loss
- liver problems
- sensitivity of skin to light, itching, eczema, rash or swelling of the skin, increased sweating, hives, skin blistering or peeling
- back pain, muscle spasm or cramps, leg pain, joint pain, muscle pain, leg cramps
- problems with sexual performance
- chest pain, general pain, influenza, abnormal physical weakness or lack of energy
- abnormal blood test results
- cough.

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

- inflammation of salivary glands inflammation of the back of the throat (pharyngitis), sinusitis

- lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body's immune system attacks the body)
- inflammation of the lining of the stomach (gastritis)
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever)
- increase in certain white blood cells (eosinophilia)
- rhabdomyolysis (a condition affecting the muscles with symptoms such as dark urine and difficulty in moving the arms or legs)
- tendon pain (tendinitis), weakness, joint pain (arthrosis)
- skin and lip cancer (non-melanoma skin cancer), with abnormal growth of skin, bumps or sores on the lips that persist for a long period of time
- loss of diabetic control
- anorexia, loss of appetite, increased cholesterol and glucose levels in the blood
- light headedness
- yellow vision (xanthopsia), increased pressure in the eye (acute angle-closure glaucoma)
- inflammation of blood vessels (vasculitis necrotising)
- kidney inflammation or impaired kidney function, glucose in the urine (glycosuria)
- fever.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of TESAR CO. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store TESAR CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in 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 TESAR CO contains:

The active substances are telmisartan and hydrochlorothiazide.

TESAR CO 40/12,5 mg: Each double-layered tablet contains telmisartan 40 mg and hydrochlorothiazide 12,5 mg.

TESAR CO 80/12,5 mg: Each double-layered tablet contains telmisartan 80 mg and hydrochlorothiazide 12,5 mg.

The other ingredients are

Crospovidone, ferric oxide red / yellow, hypromellose, lactose monohydrate, mannitol, magnesium stearate, meglumine, microcrystalline cellulose, povidone, sodium hydroxide, sodium starch glycolate.

What TESAR CO looks like and contents of the pack

TESAR CO 40/12,5 mg tablets are round, bilayer tablets with white and yellow colour with a diameter of 9,25 mm.

TESAR CO 80/12,5 mg tablets are round, bilayer tablets with white and pink colour with a diameter of 10,5 mm.

TESAR CO tablets are available in aluminium/aluminium blister strips of 28 or 30 tablets, packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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