PATIENT INFORMATION LEAFLET FOR CO-TELZA

SCHEDULING STATUS

S3

CO-TELZA 40/12,5; CO-TELZA 80/12,5 and CO-TELZA 80/25 Tablets

Telmisartan and hydrochlorothiazide

Contains sugar (lactose monohydrate and mannitol)

CO-TELZA 40/12,5 contains 310,80 mg lactose monohydrate and 50 mg mannitol.

CO-TELZA 80/12,5 contains 499,40 mg lactose monohydrate and 50 mg mannitol.

CO-TELZA 80/25 contains 486,70 mg lactose monohydrate and 50 mg mannitol.

CO-TELZA 40/12,5 contains salt (sodium, 1,93 mg).

CO-TELZA 80/12,5 contains salt (sodium, 3,85 mg).

CO-TELZA 80/25 contains salt (sodium, 3,85 mg).

Read all of this leaflet carefully before you start taking CO-TELZA

- 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.
- CO-TELZA 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 CO-TELZA is and what it is used for.

2. What you need to know before you take CO-TELZA.

3. How to take CO-TELZA.

4. Possible side effects.

5. How to store CO-TELZA.

6. Contents of the pack and other information.

1. What CO-TELZA is and what it is used for

CO-TELZA 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.

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

2. What you need to know before you take CO-TELZA

Do not take CO-TELZA:

- If you are hypersensitive (allergic) to telmisartan, hydrochlorothiazide, or other sulphonamide-derived medicines, or to any of the inactive ingredients of CO-TELZA (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 levels or high calcium levels in your blood that do not get better with treatment.
- 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).
- After previously taking other angiotensin receptor blockers (ARBs) or ACE inhibitors you have experienced swelling of your face, lips, eyelids, mouth, tongue or throat. You must never take these medicines (including CO-TELZA) 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 CO-TELZA 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 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 CO-TELZA:

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

- 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 CO-TELZA**).
- 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 including a medicine containing aliskiren (see **Do not take CO-TELZA**).
- Contact your doctor to re-evaluate your treatment if you are being treated with ACE inhibitors/angiotensin receptor blockers (ARBs) (to treat high blood pressure) together with a fluoroquinolone antibiotic (see **Do not take CO-TELZA**).
- 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 CO-TELZA**).
- 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 CO-TELZA may increase the levels of potassium in your blood and your doctor may need to regularly monitor these levels.

- If you suffer from liver problems (see **Do not take CO-TELZA**).
- 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. CO-TELZA may worsen your gout (see **Do not take CO-TELZA**).
- CO-TELZA may lower sodium and magnesium levels in your blood and taking calcium with CO-TELZA may raise the calcium levels in your blood (see **Other medicines and CO-TELZA**).
- 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 CO-TELZA. This can lead to permanent vision loss, if not treated. If you earlier 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 CO-TELZA, 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 CO-TELZA.
- CO-TELZA should not be used if you have or had skin and lip cancer (see **Do not take CO-TELZA**).
- These tablets may be less effective in lowering the blood pressure in black patients.
- If you have heart disease and experience an excessive drop in blood pressure.
- If you have a history of allergies 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 CO-TELZA.

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

Children and adolescents:

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

Other medicines and CO-TELZA

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

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

- Lithium containing medicines to treat some types of depression (see **Do not take CO-TELZA**).
- Fluoroquinolones (antibiotics that are commonly used to treat a variety of illnesses such as respiratory and urinary tract infections) (see **Do not take CO-TELZA**).
- 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, ciclosporin (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 CO-TELZA** and **Take special care with CO-TELZA**).

CO-TELZA 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, medicines that may induce "Torsade's de pointes" (irregular heart beat) such as dolasetron, erythromycin, clarithromycin, halofantrine, moxifloxacin, pimozide, chlorpromazine, ziprasidone and mizolastine.
- Non-steroidal 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 CO-TELZA 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 CO-TELZA.
- Medicines used to treat high blood sugar (diabetes), including insulin or metformin. Your doctor may want to adjust your diabetes medicine.
- Cholestyramine and colestipol resins (used to treat high cholesterol) affect the way CO-TELZA works.
- Digitalis glycosides such as digoxin (to treat heart rhythm disorder) as CO-TELZA may increase the effects of this medicine.
- Noradrenaline (used to treat low blood pressure).
- Muscle relaxants (e.g., tubocurarine) as CO-TELZA may increase the muscle relaxing effects.
- Medicines for the treatment of gout (probenecid, sulfinpyrazone and allopurinol) as CO-TELZA 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 (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) such as atropine and biperiden.
- Amantadine (medicine used to treat Parkinson's disease) as CO-TELZA may increase the risk of unwanted side effects.

- Cytotoxic medicines (e.g., cyclophosphamide, methotrexate) used to treat cancer, as CO-TELZA 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.

CO-TELZA with food, drink and alcohol

CO-TELZA can be taken with or without food.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using CO-TELZA.

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

DO NOT take CO-TELZA whilst breastfeeding your baby (see **Do not take CO-TELZA**).

CO-TELZA should not be given to women of child bearing potential unless using appropriate contraceptive methods.

Driving and using machines

CO-TELZA may cause dizziness or drowsiness.

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

CO-TELZA contains sugar (lactose monohydrate) and salt (sodium)

CO-TELZA contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 23 mg sodium per tablet, that is to say essentially ‘sodium-free’.

3. How to take CO-TELZA

Do not share medicines prescribed for you with any other person. Always use CO-TELZA exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Three strengths of CO-TELZA tablets are available; 40/12,5 mg, 80/12,5 mg and 80/25 mg.

Your doctor will decide which strength is best for you.

Adults:

The usual dose is one CO-TELZA 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:

CO-TELZA is not recommended for use in children.

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

If you take more CO-TELZA 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 an overdose may include:

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

If you forget to take CO-TELZA

If you forget to take CO-TELZA, take it 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 CO-TELZA

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

4. Possible side effects

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

If any of the following happens, stop using CO-TELZA 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 CO-TELZA. 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 (ortho-static hypotension/dizziness).
- Changes in the way your heart beats, for example, if you notice it is beating faster, 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, 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, decrease in the number (or even lack) of cells in the blood, including low red and white blood cell count.
- Decreased blood potassium (hypokalaemia), sodium (hyponatraemia) and glucose (hypoglycaemia) and increased uric acid causing gout (hyperuricaemia) levels in the blood.
- Depression, anxiety.
- Insomnia (sleep disorder), sleep disturbances, pins-and-needles sensation, drowsiness.
- 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.
- Pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).
- 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.
- 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).
- 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, bump 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.
- Restlessness.
- 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. This includes any possible side-effects not listed in this leaflet. 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 CO-TELZA.

5. How to store CO-TELZA

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused capsules in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What CO-TELZA contains:

The active substances are telmisartan and hydrochlorothiazide.

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

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

CO-TELZA 80/25: Each double-layered tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients are crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, meglumine, povidone K 25, silica colloidal anhydrous, sodium hydroxide, sodium stearyl fumarate and talc.

Contains the following colourants:

Iron oxide red (in CO-TELZA 40/12,5; 80/12,5 and 80/25) and iron oxide yellow (in CO-TELZA 80/25).

What CO-TELZA looks like and contents of the pack

CO-TELZA 40/12,5:

Biconvex, two-layered, capsule shaped uncoated tablets wherein, the hydrochlorothiazide layer is white to off white, debossed with ‘423’ and the telmisartan layer is mottled orange to reddish brown, without debossing. Hydrochlorothiazide layer may contain reddish brown specks.

CO-TELZA 80/12,5:

Biconvex, two-layered, capsule shaped uncoated tablets wherein, the hydrochlorothiazide layer is white to off white, debossed with ‘424’ and the telmisartan layer is mottled orange to reddish brown, without debossing. Hydrochlorothiazide layer may contain reddish brown specks.

CO-TELZA 80/25:

Biconvex, two-layered, capsule shaped uncoated tablets wherein, the hydrochlorothiazide layer is light yellow, debossed with ‘425’ and the telmisartan layer is mottled orange to reddish brown, without debossing. Hydrochlorothiazide layer may contain reddish brown specks.

Silver aluminium/aluminium blister strips containing 10 or 15 tablets each, packed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd

13 Pasita Street

Rosen Heights

Rosen Park

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7530

South Africa

Registration numbers

CO-TELZA 40/12,5: 51/7.1.3/0181

CO-TELZA 80/12,5: 51/7.1.3/0182

CO-TELZA 80/25: 51/7.1.3/0183