PATIENT INFORMATION LEAFLET
REGOVAL CO RANGE

SCHEDULING STATUS:

S3

REGOVAL CO 80/12,5 mg, film coated tablets

REGOVAL CO 160/12,5 mg, film coated tablets

REGOVAL CO 160/25 mg, film coated tablets

80/12,5 mg: contains 80 mg valsartan, 12,5 mg hydrochlorothiazide,

sorbitol 9,25 mg and sugar (lactose monohydrate 1,06 mg)

160/12,5 mg: contains 160 mg valsartan, 12,5 mg hydrochlorothiazide,

sorbitol 18,5 mg and sugar (lactose monohydrate 2,12 mg)

160/25 mg: contains 160 mg valsartan, 12,5 mg hydrochlorothiazide,

sorbitol 18,5 mg and sugar (lactose monohydrate 1,06 mg)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- REGOVAL 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

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

REGOVAL CO film coated tablets contain two active ingredients called valsartan and hydrochlorothiazide. Both of these ingredients help to control high blood pressure (hypertension). Valsartan belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure (hypertension). Hydrochlorothiazide is a diuretic (also known as “water tablet”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

REGOVAL CO is used

- to treat mild to moderate high blood pressure.
- for patients whose blood pressure has been stabilised at the same dosages of the individual components given together.

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

Do not take REGOVAL CO:

- if you are hypersensitive (allergic) to valsartan, hydrochlorothiazide, sulphonamide-type medicines, or any of the other ingredients of REGOVAL CO (see section 5)
- if you have or had skin and lip cancer
- if, after previously taking other angiotensin receptor blockers (ARBs) or ACE inhibitors, you have experienced swelling of your face, lips, eye lids, mouth, tongue or throat. You must never take these medicines, including REGOVAL CO, again
- if you suffer from heart disease, including a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM – thickening of the muscle of the heart)
- 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 have a disease of the heart valves called aortic stenosis in which the opening is narrowed
- if you are treated with ACE inhibitors/angiotensin receptor blockers together with fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin, contact your doctor to re-evaluate your treatment
- if you are currently taking water tablets containing spironolactone, triamterene or amiloride (medicines that increase the rate of urination)
- if you are currently taking lithium (a mood stabiliser). Concomitant administration with REGOVAL CO may lead to toxic blood concentrations of lithium
- if you are pregnant or breastfeeding your baby
- if you have severely impaired liver function or liver cirrhosis

- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you are taking a medicine that contains aliskiren (used in the treatment of high blood pressure)
- if you are suffering from gout
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- if you have Addison's disease (a hormonal disorder).

Warnings and precautions

Take special care with REGOVAL CO:

- **Should you become pregnant while taking REGOVAL CO, stop taking the tablets immediately and contact your doctor. Your doctor may consider switching your medication to a different treatment (see Do not take REGOVAL CO).**
- if you are on a low-salt diet, have lost a lot of fluids recently (due to excessive sweating, hot weather, exercising, diarrhoea, vomiting or dialysis) or are taking high doses of water tablets as you may experience dehydration or a serious drop in blood pressure (hypotension) with symptoms including feeling dizzy when standing up
- if you take salt substitutes containing potassium or you have high potassium levels in your blood, as REGOVAL CO may increase the levels of potassium in your blood and your doctor may need regularly to monitor these levels

- if you take magnesium tablets, REGOVAL CO may lower magnesium levels in your blood and taking calcium with REGOVAL CO may raise the calcium levels in your blood (see **Other medicines with REGOVAL CO**)
- if you have a kidney disorder
- if you have a liver disorder
- if you have a heart disease or have had a heart attack
- if you have diabetes and are being treated for it
- if you have gout. REGOVAL CO may worsen your gout
- if you have high cholesterol
- if you have systemic lupus erythematosus (also called “lupus” or “SLE”). (Symptoms include pain in the joints or weakness in the muscles)
- if you experience fatigue or muscle weakness as these may be symptoms of a condition called hyperkalaemia
- 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 develop sensitivity of the skin to sun
- 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 to a week of taking REGOVAL 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 a kidney transplant (see **Do not take REGOVAL CO**)
- if you have had skin cancer or if you develop an unexpected skin lesion (unusual growth of skin). Treatment with hydrochlorothiazide as in REGOVAL 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 REGOVAL CO
- REGOVAL CO should not be used if you have or had skin and lip cancer

The first dose of REGOVAL CO may cause a bigger fall in blood pressure than the following doses. You may notice this as a feeling of weakness or dizziness, and it may help to lie down. Contact your doctor if you are worried. In order to prevent an extreme fall in blood pressure with the first dose, existing therapy with diuretics (water tablets) should be discontinued 2 to 3 days before taking REGOVAL CO. Your doctor may check the electrolyte content of your blood thereafter.

Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin.
Your doctor may request tests to monitor your condition before or during treatment.

Other medicines and REGOVAL CO

Always tell your healthcare provider if you are taking any other medicine. (This includes

complementary or traditional medicines.)

The following medications, may interact with REGOVAL CO:

- Water tablets such as spironolactone, triamterene or amiloride) and certain other diuretics.
- Potassium supplements or medicines containing potassium. This may include your daily multivitamin supplement.
- Other medicines from the same class (angiotensin II receptor antagonists or ACE inhibitors) to lower blood pressure.
- Lithium (used in the treatment of mood disorders)
- Muscle relaxants (e.g. tubocurarine) as REGOVAL CO may increase the effects of these medicines.
- 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 REGOVAL CO and may affect the kidney function or worsen an existing kidney problem.
- Medicines to control heart rhythm (such as digoxin) may increase the risk of side effects such as blood and heart rhythm disorders.
- Alcohol, narcotics or any other medicines that work on the nervous system as they may increase the effects of REGOVAL CO.
- Medicines used to treat high blood sugar (diabetes), including insulin or metformin as REGOVAL CO may increase your sugar levels. Your doctor may

want to adjust your diabetes medication.

- Medicines that may increase blood sugar levels, such as diazoxide or beta blockers may increase the risk of hyperglycaemia (high blood sugar).
- Amantadine (used to treat Parkinson's disease) as REGOVAL CO may increase the risk of unwanted side effects.
- Medicines for the treatment of gout (probenecid, sulfinpyrazone and allopurinol) as REGOVAL CO may reduce its effect.
- Cytotoxic medicines (e.g. cyclophosamide, methotrexate) used to treat cancer, as REGOVAL CO may affect the way they work.
- Atropine and biperiden (used in the treatment of Parkinson's disease) as REGOVAL CO may increase its effect.
- Methyldopa (used to treat high blood pressure) may increase the risk of anaemia.
- Cholestyramine (used to treat high cholesterol) as these may reduce the effects of REGOVAL CO. These medicines should be taken at least an hour before taking REGOVAL CO.
- Vitamin D supplements or calcium salts may require additional blood tests and dosage adjustment during treatment with REGOVAL CO.
- Ciclosporin (used in organ transplants) may increase the risk of side effects such as gout.
- Corticosteroids, kaliuretic diuretics, amphotericin, penicillin G and salicylic acid derivatives (used to treat infections and inflammations) as these may affect the way REGOVAL CO works.

- Some laxatives may affect your electrolyte balance.
- Pressor amines, e.g. epinephrine (adrenaline) used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies.
- 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 REGOVAL CO** and **Warnings and precautions**).
- Medicines that may induce “torsade’s de pointes” (irregular heartbeat), such as antidysrhythmics (medicines used to treat heart problems, such as disopyramide, procainamide, quinidine and sotalol) and some antipsychotics, such as haloperidol, thioridazine and pimozide.
- Some antibiotics (rifampicin), medicines used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of REGOVAL CO.

Please also inform your doctor you are taking REGOVAL CO if you will be undergoing a radiographic procedure and will be given iodine contrast media.
REGOVAL CO may interfere with thyroid function tests.

Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin.

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REGOVAL CO with food and drink

REGOVAL CO is best taken every morning at the same time.

REGOVAL CO tablets can be taken with or without food.

Pregnancy and breastfeeding

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

REGOVAL CO is contraindicated in pregnancy and breastfeeding as it can harm your unborn baby.

Safety in pregnancy and breastfeeding has not been established (see Do not take REGOVAL CO).

When pregnancy is planned or confirmed, you should stop taking REGOVAL CO.

If you are taking REGOVAL CO, you should use contraception.

If you are taking REGOVAL CO, you should not breastfeed your baby.

Driving and using machines:

REGOVAL CO may cause some people to become dizzy or tired.

Do not drive a vehicle or operate any machinery before you know how REGOVAL CO affects you.

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

REGOVAL CO contains lactose

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

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

REGOVAL CO contains sorbitol (a source of fructose). If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance, a rare genetic disorder, talk to your doctor before you take this medicine.

3. How to take REGOVAL CO

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

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

The tablets should be swallowed with a glass of water or juice.

It is recommended to take the tablets at the same time every day.

Adults:

The usual dose of REGOVAL CO is 1 tablet once a day.

The maximum effect of REGOVAL CO is usually seen within 2 to 4 weeks.

Your doctor will tell you how long your treatment with REGOVAL CO will last. Do not stop treatment early because this may cause your high blood pressure to get worse.

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

If you take more REGOVAL 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:

- severe dizziness and/or fainting

If you forget to take REGOVAL CO:

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

If you stop taking REGOVAL CO

Your doctor will tell you how long your treatment with REGOVAL CO will last.

It is important that you continue the course of treatment. Do not stop taking REGOVAL CO unless your doctor tells you to do so.

4. Possible side effects

REGOVAL CO can have side effects.

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

If any of the following happens, stop using REGOVAL 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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to REGOVAL 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)
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- fainting (syncope)

- kidney problems (passing less urine than is normal for you), abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine
- 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, jaundice (yellow discolouration of the skin and eyes))
- rhabdomyolysis (a condition affecting the muscles with symptoms such as muscle pain, weakness, vomiting and confusion, dark urine and irregular heartbeat).

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 a low number of white blood cells which can cause vulnerability to infections
- blood tests showing decreased levels of sodium, potassium, magnesium and other body chemicals which can cause irregular heartbeats, increased cholesterol, muscle cramps, weakness, tremors, fatigue, confusion and seizures excess amount of uric acid in the blood, gout, which can cause pain in the joints (hyperuricemia)
- headache, dizziness, cough
- loss of appetite

- hives
- back pain, joint pain, spasm
- problems with sexual performance

Less frequent side effects:

- viral infections, upper respiratory tract infections, sore throat, inflammation of tissues lining the sinuses (sinusitis), blocked or runny nose, inflammation of the mucous membrane in the nose (rhinitis)
- increased bleeding and bruising
- anorexia, dehydration
- depression, sleeping disorders
- vertigo (loss of balance and dizziness), ringing or buzzing in the ears
- lung infection, excess watery fluid in the lungs (symptoms include shortness of breath, feeling of suffocating, fever, chills, wheezing)
- stomach pain or discomfort, bloating, constipation, diarrhoea, nausea, vomiting, inflammation of a salivary gland (symptoms include fever, chills, pain when opening mouth)
- sensitivity to light, dry skin, blistering or peeling of the skin
- muscle pain, sprains and strains

  general tiredness or weakness, lack of energy, fluid retention.

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

- blood tests showing a decrease or changes to the content of your blood cells including a reduction of iron in your red blood cells
- blood tests or urine test showing increased levels of potassium, calcium, sugar or low levels of chloride ion
- restlessness, fever, tingling or pricking in hands, feet or lips (feeling of “pins or needles”)
- blurred vision, worsening eyesight, seeing things yellow, severe eye pain, watery eyes
- itching, inflammation of the skin, rash, redness of the skin, hair loss
- 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.
- high fever, sweating, chills

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 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 REGOVAL CO.

5. How to store REGOVAL CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blisters in 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 REGOVAL CO contains

The active substances are valsartan and hydrochlorothiazide.

REGOVAL CO 80/12,5 mg: Each film coated tablet contains 80 mg valsartan and 12,5 mg hydrochlorothiazide.

REGOVAL CO 160/12,5 mg: Each film coated tablet contains 160 mg valsartan and 12,5 mg hydrochlorothiazide.

REGOVAL CO 160/25 mg: Each film coated tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide.

The other ingredients are:

The other ingredients are colloidal anhydrous silica, colloidal silicon dioxide, crospovidone, hypromellose, iron oxide brown (160/12,5 mg and 160/25 mg tablets), iron oxide red (80/12,5 mg and 160/12,5 mg tablets), iron oxide yellow (160/25 mg tablets),

lactose monohydrate, macrogol 4000, magnesium carbonate, microcrystalline cellulose, Opadry white, povidone, pregelatinised starch, sodium lauryl sulphate, sodium stearyl fumarate, sorbitol powder and titanium dioxide.