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

Valsartan and hydrochlorothiazide

REGOVAL CO contains sorbitol (9,25 mg in a 80/12,5 mg tablet and 18,5 mg in each 160/12,5 mg and 160/25 mg tablet) and sugar (lactose monohydrate) (1,06 mg in a 80/12,5 mg tablet and 2,12 mg in 160/12,5 mg and 160/25 mg tablet)

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, pharmacist, nurse or other healthcare provider.
- 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

1. What REGOVAL CO is and what it is used for
2. What you need to know before you take REGOVAL CO
3. How to take REGOVAL CO
4. Possible side effects
5. How to store REGOVAL CO
6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET

REGOVAL CO RANGE

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 to any of the ingredients of REGOVAL CO (see section 6)
- 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 suffer from a severe kidney disease where you are unable to produce urine (anuria)
- 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/ARBs together with fluoroquinolone antibiotics 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)
- if you have porphyria (a rare hereditary blood disorder that can cause nerve or skin problems).

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 to regularly monitor these levels
- if you have low levels of sodium in your blood (with or without symptoms such as nausea, disorientation, lack of interest, enthusiasm, or concern), your doctor may need to regularly monitor these levels
- if you have low levels of potassium in your blood, you may experience unwanted side effects. Your doctor may need to correct your potassium blood levels before starting therapy with REGOVAL-CO
- 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
- if you are taking other medicines to lower blood pressure, called ACE inhibitors or aliskiren (see Do not take REGOVAL CO).

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 - 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/ARBs 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) (see Do not take REGOVAL CO)
- muscle relaxants (e.g. tubocurarine), as REGOVAL CO may increase the effects of these medicines
- nonsteroidal anti-inflammatory drugs (NSAIDs) to treat pain and arthritis (such as ibuprofen, indometacin 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 which 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 and colestipol (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 inflammation), as these may affect the way REGOVAL CO works
- some laxatives may affect your electrolyte balance
- pressor amines, e.g., adrenaline (epinephrine) used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies
- aliskiren and similar medicines, as these 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 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
- medicines such as antidepressants, antipsychotics (mood stabilizers), antiepileptics as these may affect the sodium levels in your blood.

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/ARBs together with a fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin.

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 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 9,25 mg sorbitol in a 80/12,5 mg tablet and 18,5 mg in each 160/12,5 and 160/25 mg tablet.

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 told 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.

REGOVAL CO tablets can be taken with or without food.

Adults:

The usual dose of REGOVAL CO is 1 tablet once a day. The maximum effect of REGOVAL CO is usually seen within 2 - 4 weeks.

Children:

REGOVAL CO is not indicated for use in children.

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

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 healthcare provider for advice.

If any of the following happens, stop taking 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
- fainting (syncope).

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)
- red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of toxic epidermal necrolysis or erythema multiforme)
- 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)
- irregular or abnormal rhythm
- agranulocytosis (serious condition that occurs when the body does not make enough white blood cells, making it harder for the body to fight infection).

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)
- cough
- loss of appetite, nausea, vomiting
- hives
- 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
- headache, dizziness, tingling or pricking in hands, feet, or lips (feeling of “pins or needles”)
- 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, itching
- back pain, joint pain, muscle pain, sprains and strains
- general tiredness or weakness, lack of energy, fluid retention.
- abnormal blood test results, hemolytic anemia (a rare blood disorder in which red blood cells are rapidly destroyed) bone marrow failure (symptoms include weakness, bruising, frequent infections).

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
- aplastic anaemia (a rare but serious blood condition that occurs when your bone marrow cannot make enough new blood cells)

- blood tests or urine tests showing increased levels of potassium, calcium, sugar or low levels of chloride ion
- restlessness, fever
- blurred vision, worsening eyesight, seeing things yellow, severe eye pain, watery eyes
- 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
- muscle spasm.

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, pharmacist or nurse. 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 REGOVAL 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 REGOVAL 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 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:
Tablet cores: colloidal anhydrous silica, colloidal silicon dioxide, crospovidone, magnesium carbonate, microcrystalline cellulose, pregelatinised starch, povidone, sodium lauryl sulphate, sodium stearyl fumarate, sorbitol powder.
Film coating: opadry white (hypromellose, lactose monohydrate, macrogol 4000 and titanium dioxide).
Colouring agents: 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),

What REGOVAL CO looks like and contents of the pack

REGOVAL CO 80/12,5 mg: Cylindrical, biconvex, pink film coated tablets.
REGOVAL CO 160/12,5 mg: Cylindrical, biconvex, reddish film coated tablets.
REGOVAL CO 160/25 mg: Cylindrical, biconvex, brown film coated tablets.

REGOVAL CO tablets are available in clear PVC/PE/PVDC/aluminium blister strips. Pack sizes of 14, 28, 30, 56, 98 or 280 tablets are packed in a printed outer carton.

PATIENT INFORMATION LEAFLET

REGOVAL CO RANGE

Holder of Certificate of Registration

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REGOVAL CO 80/12,5 mg: 4817

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