PATIENT INFORMATION LEAFLET
REGOVAL RANGE

SCHEDULING STATUS:

S3

REGOVAL 40 mg film coated tablets

REGOVAL 80 mg film coated tablets

REGOVAL 160 mg film coated tablets

40 mg: valsartan 40 mg, sorbitol 4,6 mg, sugar (lactose monohydrate 0,5 mg)

80 mg: valsartan 80 mg, sorbitol 9,3 mg, sugar (lactose monohydrate 1,1 mg)

160 mg: valsartan 160 mg, sorbitol 18,5 mg, sugar (lactose monohydrate 2,2 mg)

Read all of this leaflet carefully before you start taking REGOVAL

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

REGOVAL contains valsartan, class of medicines known as angiotensin II receptor antagonists.

REGOVAL can be used for three different conditions:

- To treat mild to moderate high blood pressure.
- To treat patients after a recent heart attack.
- To treat symptomatic heart failure.

2. What you need to know before you take REGOVAL

Do not take REGOVAL:

- if you are hypersensitive (allergic) to valsartan or any of the other ingredients of REGOVAL (see section 5)
- 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, again
- if you suffer from heart disease, including a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM)
- if you suffer from a severe kidney disorder
- if you suffer from a narrowing of the kidney artery

- if you have recently undergone a kidney transplant (received a new kidney) or removal
- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride. REGOVAL increases the amount of potassium in your blood
- if you have a severe liver disease
- if you are currently taking lithium (used to treat depression and mood disorders). REGOVAL increases the amount of lithium in your blood
- if you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding and Fertility**)
- if you are currently taking aliskiren-containing products (used to treat high blood pressure).
- 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

Warnings and precautions

Take special care with REGOVAL:

- if you become pregnant whilst taking REGOVAL, you should stop taking your medicine immediately and inform your doctor. Your doctor should switch you to another medicine
- if you are on a low-salt diet, have lost a lot of fluids recently (due to excessive sweating, diarrhoea, vomiting, dialysis) or are taking high doses of water tablets (diuretics). The first dose of REGOVAL 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. Your doctor should check the electrolyte content of your blood thereafter

- if you have a kidney disorder because the side effects of REGOVAL may be increased
- if you have a mild liver disorder, (see Do not take REGOVAL)
- if you have a heart disease or have had a heart attack, your doctor should monitor your kidney function
- if you are already taking other medicines to treat heart failure such as ACE-inhibitors or aliskiren-containing medicines used to treat high blood pressure.

Other medicines and REGOVAL

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

The following medicines may interact with REGOVAL

- Medicines such as aliskiren, ACE inhibitors and beta blockers used to lower high blood pressure.
- Lithium, used for depression (see **DO NOT TAKE REGOVAL**).
- Medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium. This may include your daily multivitamin.
- Diuretics (water tablets) or other blood pressure lowering medicines (see **DO NOT TAKE REGOVAL**).

- 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
- Non-steroidal anti-inflammatory medicines (NSAIDs) including aspirin (used for inflammation and pain).

REGOVAL with food and drink

You can take REGOVAL with or without food.

Pregnancy and breastfeeding and fertility

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

Do not take REGOVAL if you are pregnant, planning to become pregnant or if you are breastfeeding your baby (see **Do not take REGOVAL**).

Women of childbearing age should ensure effective contraception.

Driving and using machines:

REGOVAL may make you feel dizzy.

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

REGOVAL contains lactose and sorbitol

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

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

REGOVAL 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

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

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

Adults:

The usual dose is:

High blood pressure: The usual dose is 80mg daily. In some cases, your doctor may prescribe higher doses (e.g. 160mg or 320mg). He/she may also combine REGOVAL with an additional medicine e.g. a diuretic (water tablet).

Adult patients after a recent heart attack: After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate.

REGOVAL can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Heart failure: Treatment starts generally with 40mg twice daily. Your doctor will increase the dose gradually over several weeks to 80 mg and 160mg twice daily (maximum dose). The final dose depends on what you as an individual patient can tolerate.

REGOVAL can be given together with other treatment for heart failure: your doctor will decide which treatment is suitable for you.

Your doctor will determine your dose according to your condition.

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

Your doctor will tell you how long your treatment with REGOVAL will last. Do not stop treatment early, even if you feel better.

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

If you take more REGOVAL 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. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Symptoms of overdose may include:

You may experience severe dizziness or fainting, weakness, rapid shallow breathing, cold and clammy skin.

If you forget to take REGOVAL:

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 a forgotten dose.

If you stop taking REGOVAL

Stopping your treatment with REGOVAL may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

REGOVAL can have side effects.

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

If any of the following happens, stop using REGOVAL 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

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

- loss of water or body fluids (dehydration)
- feeling sick, tired, muscle weakness or tingling sensations, irregular heartbeat or shortness of breath (hyperkalaemia)

- Henoch-Schönlein purpura (inflammation of small blood vessels with symptoms such as rash or many small bruises, swollen and sore joints, abdominal /stomach pain and bloody urine)
- rhabdomyolysis (a condition affecting the muscles with symptoms such as muscle pain, weakness, vomiting,confusion, dark urine)
- decreased kidney function (signs of renal impairment)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- heart failure (signs include breathlessness, extreme tiredness, swelling in the ankles, feet, legs, abdomen and veins in the neck

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:

- viral infections
- fever, sore throat or mouth ulcers due to infections (symptoms of low levels of white blood cells also called neutropenia)
- dizziness or feeling lightheaded (including when standing up)
- low blood pressure with or without symptoms, such as dizziness and fainting when standing up
- kidney problems

Less frequent side effects:

- sore throat, sinusitis, blocked or runny nose, cough

- unusual bleeding or bruising (signs of thrombocytopenia)
- swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
- blood tests showing an increase of level of potassium in the blood (hyperkalaemia, which can trigger muscle spasms, abnormal heart rhythm in severe cases)
- decreased levels of sodium in the blood, which can cause confusion, seizures, fatigue and low levels of consciousness (hyponatraemia)
- problems sleeping, decreased sex drive
- headache
- feeling of spinning when standing still (vertigo)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- diarrhoea, feeling sick, stomach pain, taste disturbances, taste loss
- liver problems
- skin rash, itchy skin
- joint pain, back pain, muscle cramps
- kidney problems
- lack of strength, feeling extremely tired or weak, swelling in the feet and ankles

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

- rhinitis with symptoms such as irritation and swelling of the mucous membrane in the nose (such as hayfever)
- migraine
- respiratory tract disorders affecting the lungs and breathing

- damage to the liver with common first sign as jaundice (yellowing of skin and whites of the eyes)
- Psoriasis, dermatitis bullous (blister type rash)
- decrease of red bloods cells in the blood (which can lead in severe cases to anaemia)

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.

5. How to store REGOVAL

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not remove from 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

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REGOVAL RANGE

What REGOVAL contains

The active substance is valsartan.

REGOVAL 40 mg: Each film coated tablet contains 40 mg valsartan.

REGOVAL 80 mg: Each film coated tablet contains 80 mg valsartan.

REGOVAL 160 mg: Each film coated tablet contains 160 mg valsartan.

The other ingredients are:

Tablet cores:

Colloidal anhydrous silica, crospovidone, magnesium carbonate, microcrystalline cellulose, povidone, pregelatinised starch, sodium stearyl fumarate, sodium lauryl sulphate and sorbitol.

Film-coating:

iron oxide brown (160 mg tablet), iron oxide red (80 mg tablet), iron oxide yellow (40 mg and 160 mg tablets) and Opadry white (containing Hypromellose, lactose monohydrate, macrogol and titanium dioxide).