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

REGOVAL 320 mg film coated tablets

Valsartan

REGOVAL 40 mg tablets contain sorbitol 4,6 mg and sugar (lactose monohydrate) 0,5 mg per tablet.

REGOVAL 80 mg tablets contain sorbitol 9,3 mg and sugar (lactose monohydrate) 1,1 mg per tablet.

REGOVAL 160 mg tablets contain sorbitol 18,5 mg and sugar (lactose monohydrate) 2,2 mg per tablet.

REGOVAL 320 mg tablets contain sorbitol 37 mg and sugar (lactose monohydrate) 4,3 mg per tablet.

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, pharmacist, nurse or other healthcare provider.
- 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
2. What you need to know before you take REGOVAL
3. How to take REGOVAL

4. Possible side effects
5. How to store REGOVAL
6. Contents of the pack and other information

1. What REGOVAL is and what it is used for

Valsartan belongs to a class of medicines known as angiotensin II receptor blockers, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

REGOVAL can be used for three different conditions:

- to treat mild to moderate high blood pressure in adults
- to treat adult patients after a recent heart attack (myocardial infarction)
- to treat symptomatic heart failure in adult patients.

2. What you need to know before you take REGOVAL

Do not take REGOVAL:

- if you are hypersensitive (allergic) to valsartan, or to any of the ingredients of REGOVAL (see section 6)
- if you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again
- if you suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- if you suffer from obstruction of blood vessels to your heart or kidneys
- if you suffer from severe kidney function impairment
- if you suffer from porphyria
- if you are currently taking lithium

- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride
- if you are taking fluoroquinolones (antibiotics to treat infections)
- if you have kidney problems while you are taking a blood pressure lowering medicine called aliskiren
- if you have a high level of sugar in the blood and you are suffering from type 2 diabetes mellitus while you are taking a blood pressure lowering medicine called aliskiren
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with REGOVAL:

- if you have liver disease
- if you have severe kidney disease or if you are undergoing dialysis
- if you are suffering from a narrowing of the kidney artery
- if you have recently undergone kidney transplantation (received a new kidney)
- if you are treated after a heart attack or for heart failure, your doctor may check your kidney function
- if you have severe heart disease other than heart failure or heart attack
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals
- if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of REGOVAL is not recommended
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics)

- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another medicine (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking REGOVAL, stop taking REGOVAL immediately and never take it again. See section 4 ‘Possible side effects’
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
  - aliskiren
- if you are being treated with an ACE inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example spironolactone, eplerenone) or beta-blockers (for example metoprolol).

Contact your doctor to re-evaluate your treatment. If you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic.
Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g., potassium) in your blood at regular intervals.

Children and adolescents

The safety and efficacy of REGOVAL have not been established in children.

Other medicines and REGOVAL

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
The effect of the treatment can be influenced if REGOVAL is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions,
or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- other medicines that lower blood pressure, especially water tablets (diuretics), ACE-inhibitors, angiotensin II receptor blockers or aliskiren (blood pressure pills)

- fluoroquinolone antibiotics (to treat or prevent certain bacterial infections) when taken together with medicines that lower blood pressure
- medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin
- certain type of pain killers called nonsteroidal anti-inflammatory medicines (NSAIDs)
- lithium, a medicine used to treat some types of psychiatric illness
- some antibiotics (rifamycin group), a medicine 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
- if you are being treated after a heart attack, a combination with ACE inhibitors (a medicine to treat heart attack) is not recommended
- if you are being treated for heart failure, a triple combination with ACE inhibitors and beta blockers (medicines to treat heart failure) is not recommended.

Your doctor may need to change your dose and/or to take other precautions:

- if you are being treated with an ACE inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta- blockers (for example metoprolol).

REGOVAL with food and drink

You can take REGOVAL tablets with or without food.

Swallow REGOVAL tablets with a glass of water.

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.

Do not take REGOVAL if you are pregnant, are considering becoming pregnant or are breastfeeding.

Use of similar medicines has been associated with serious harm to the unborn child.

Your doctor will discuss the potential risk of taking REGOVAL during pregnancy with you.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines

Like many other medicines used to treat high blood pressure, REGOVAL may cause dizziness and affect the ability to concentrate.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

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

3. How to take REGOVAL

Do not share medicines prescribed for you with any other person. Always take REGOVAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

High blood pressure: The usual starting dose is 80 mg of REGOVAL once daily. In some cases, your doctor may prescribe higher doses (the dose can be increased to 160 mg and to a maximum

of 320 mg). REGOVAL may also be administered with other medicines for high blood pressure.

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.

Adult patients with heart failure: Treatment starts generally with 40 mg twice daily. Your doctor will increase the 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 failure, and your doctor will decide which treatment is suitable for you.

Children:

REGOVAL tablets are only for adults and should not be taken by children and adolescents up to 18 years.

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

Symptoms of overdose may include:

- severe dizziness and/or fainting, contact your doctor immediately and lie down.

If you forget to take REGOVAL

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. 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 healthcare provider 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.

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:

- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)

- severe blistering of the skin (bullous dermatitis).

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:

- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment e.g., reduced urine, swelling of feet and legs).

Less frequent side effects:

- sudden loss of consciousness (syncope)
- dizziness
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- heart failure
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- cough, sore throat, hay fever, inflamed sinuses
- abdominal pain, nausea, diarrhoea
- tiredness, weakness, fluid retention causing swelling (oedema)
- back pain
- sleeplessness
- low sex drive.

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

- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of

serum sickness)

- purplish-red spots, fever, itching (signs of inflammation of blood vessels, also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells, also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms, abnormal heart rhythm in severe cases)
- 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)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)
- headache.

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of REGOVAL. 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

Store all medicines out of reach of children.

Store at or below 25 ºC.

Protect from moisture.

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 REGOVAL contains:

The active ingredient 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.

REGOVAL 320 mg: Each film coated tablet contains 320 mg valsartan.

The other ingredients are:

Tablet cores:

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

Film-coating:

Hypromellose, indigo carmine aluminium lake (320 mg), iron oxide brown (160 mg & 320 mg tablets), iron oxide red (80 mg & 320 mg tablets), iron oxide yellow (40 mg & 160 mg), lactose monohydrate, macrogol and titanium dioxide.

What REGOVAL looks like and contents of the pack

REGOVAL 40 mg: Cylindrical, biconvex, scored on one side, yellow, film coated tablet.

REGOVAL 80 mg: Cylindrical, scored on one side, pink, film coated tablet.

REGOVAL 160 mg: Cylindrical, biconvex, scored on one side, ochre, film coated tablet.

REGOVAL 320 mg: Oblong, scored on one side, greyish-violet film coated tablets.

The tablets are packaged in PVC-PE- PVDC (triplex)/aluminium blister packs of thirty (30) tablets placed in an outer carton.

Holder of Certificate of Registration

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REGOVAL 40 mg: A43/7.1.3/0547*

PATIENT INFORMATION LEAFLET

REGOVAL RANGE

REGOVAL 80 mg: A43/7.1.3/0548

REGOVAL 160 mg: A43/7.1.3/0549

REGOVAL 320 mg: A47/7.1.3/0693

*Not all strengths are marketed

NAMIBIA:

REGOVAL 80 mg: NS2 22/7.1.3/0035

REGOVAL 160 mg: NS2 22.7.1.3/0036