PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

REVATIO® film-coated tablets

Sildenafil citrate

Contains sugar

Each REVATIO film-coated tablet contains 0,735 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking REVATIO

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

1. What REVATIO is and what it is used for

REVATIO is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). REVATIO brings down blood pressure by widening the blood vessels including the vessels in the lungs. REVATIO belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

2. What you need to know before you take REVATIO

Do not take REVATIO:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of REVATIO (listed in section 6).
- If you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of angina pectoris (or “chest pain”). REVATIO can cause a serious increase in the effects of these medicines. Tell your doctor if you are taking any of these medicines. If you are not certain, ask your doctor or pharmacist.
- If you are taking riociguat. This medicine is used to treat high blood pressure in the lungs and high blood pressure in the lungs due to blood clots). PDE5 inhibitors such as REVATIO have been shown to increase the blood pressure lowering effects of this medicine. If you are taking riociguat or are unsure, tell your health care provider.
- If you are taking erythromycin, ketoconazole or itraconazole to treat fungal infections.
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV.
- If you have a severe liver problem or severe kidney disease.
- If you have hypotension (blood pressure less than 90/50 mmHg).

Warnings and precautions

Take special care with REVATIO:

- If you have low blood pressure or have lost a large amount of body fluids (dehydration) which can occur when you sweat a lot or do not drink enough liquids. This can happen if you are sick with a fever, vomiting or diarrhoea.
- If you have a severe heart problem, recently had a stroke or a heart attack.
- If you have any disease or deformity of the penis, or any disease that may predispose you to this condition, such as an abnormality of red blood cells (sickle cell anaemia), cancer of bone marrow (multiple myeloma) or cancer of the blood cells (leukaemia).
- Prolonged and sometimes painful erections have been reported in men after taking REVATIO. If you have an erection, which lasts continuously for more than 4 hours, stop taking REVATIO and contact your health care provider immediately (see also section 4).
- If you currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems with nose bleeds.

- If your disease is due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.
- If you have a certain rare inherited eye disease called retinitis pigmentosa.
- A large-scale study found evidence of an increased risk of retinal detachment with regular use of PDE5 inhibitors like REVATIO. If you experience symptoms of retinal detachment (flashes of light, black spots, a curtain-like shadow in your vision or a limited field of vision), see an ophthalmologist immediately.
- If you have a certain rare eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION). This causes loss of blood flow to the optic nerve (which is the cable that connects the eye to the brain) and causes decreased or loss of vision. In the event of sudden change or loss of vision, stop taking REVATIO immediately and seek immediate medical attention.
- If you use REVATIO together with other medicines for pulmonary arterial hypertension or erectile dysfunction.

Special considerations for patients with kidney or liver problems

- You should tell your doctor if you have kidney or liver problems.

Children and adolescents

REVATIO should not be given to children under the age of 18.

Other medicines and REVATIO

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

- REVATIO may cause a serious increase in the effects of medicines called nitrates and nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often used for the relief of angina pectoris (or “chest pain”). You should not take REVATIO if you are taking these medicines.
- Tell your doctor or pharmacist if you are already taking riociguat.
- If you are taking erythromycin, clarithromycin or telithromycin (antibiotics used to treat certain bacterial infections), or ketoconazole or itraconazole (used to treat fungal infections), you should not take REVATIO.
- If you are taking ritonavir or saquinavir therapy for the treatment of HIV, you should not take REVATIO.
- If you are taking bosentan therapy for pulmonary hypertension, ask your doctor or pharmacist for advice before taking REVATIO, as your dose may need to be adjusted.
- If you are taking alpha-blocker therapy for the treatment of high blood pressure or prostate problems,

ask your doctor or pharmacist for advice before taking REVATIO.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

If you are pregnant, or think you might be pregnant, ask your doctor or pharmacist for advice before taking REVATIO.

You should not take REVATIO if you are pregnant.

Breastfeeding

REVATIO passes into your breast milk at very low levels and would not be expected to harm your baby.

If you are breastfeeding, ask your doctor for advice before taking REVATIO.

Driving and using machines

REVATIO can cause dizziness and effects on vision. You should be aware of how you react to REVATIO before you drive or operate machinery.

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

REVATIO contains lactose

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

3. How to take REVATIO

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

Always take REVATIO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 20 mg three times a day (taken 6 to 8 hours apart) swallowed with or without food.

Your doctor will tell you how long your treatment with REVATIO will last. If you have the impression that the effect of REVATIO is too strong or too weak, tell your doctor or pharmacist.

If you take more REVATIO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take REVATIO

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

REVATIO can have side effects.

Not all side effects reported for REVATIO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking REVATIO, please consult your health care provider for advice.

If any of the following happens, stop taking REVATIO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Sudden decrease or loss of vision.

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

- Chest pain.
- Changes in the way your heart beats.
- Signs of recurrent infections such as fever, flu-like symptoms, bronchitis, bladder or kidney infections.

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:

- Cellulitis.

- Flu-like symptoms.
- Sinusitis.
- Anaemia.
- Fluid retention.
- Difficulty sleeping.
- Anxiety.
- Headache.
- Migraine.
- Trembling or shaking (tremor).
- Burning sensation.
- Prickling sensation (paraesthesia) of hands, arms, feet and legs.
- Numbness (hypoaesthesia).
- Effects on vision and eyes (such as light sensitivity and irritation, bleeding).
- Dizziness.
- Flushing.
- Bronchitis.
- Nosebleed.
- Rhinitis (runny nose).
- Cough.
- Diarrhoea.
- Gastrointestinal discomfort (such as indigestion/heartburn, haemorrhoids and bloating).
- Hair loss.
- Redness of the skin (erythema).
- Pain in the arms or legs.
- Back pain.
- Muscle aches.
- Breast enlargement.
- Increased body temperature.
- Weight increase.

A sudden decrease or loss of hearing in one or both ears, with or without ringing in the ears and dizziness has been reported. You should contact your doctor as soon as you become aware of the hearing loss.

Additional side effects that have been reported in patients taking sildenafil (the active ingredient of REVATIO) for different indications include the following:

- Low blood pressure.
- Chest pain.
- Fainting.
- Irregular heartbeat and palpitations.
- Heart disease.
- Blood disorders.
- Thirst.
- Gout.
- Diabetes and elevated blood sugar levels.
- Swelling of hands and feet due to retained fluid.
- Elevated blood uric acid and sodium levels.
- Disturbance in coordination, muscle rigidity, decrease in reflexes.
- Depression, drowsiness, abnormal dreams.
- Temporary vision loss and decreased vision.
- Eye infections.
- Cataracts, dry eyes, eye pain.
- Ringing in the ears.
- Deafness.
- Ear pain.
- Nasal congestion, asthma, difficulty breathing, sinusitis.
- Sore throat, increased mucus.
- Vomiting, inflammation of the gastrointestinal tract.
- Swollen tongue, mouth and gums, difficulty swallowing, dry mouth.
- Abnormal liver function tests.
- Rectal bleeding.

- Skin rash, itching, sweating, skin ulcer, contact dermatitis, peeling of the skin.
- Arthritis, bone and body pain, muscle weakness.
- Inflammation of the bladder, loss of bladder control or need to urinate frequently especially at night, blood in the urine.
- Breast enlargement.
- Premature ejaculation.
- Painful and increased erections.
- Facial swelling, sensitivity to light, shock, lack of energy, pain, chills, accidental fall and injury, pain in the belly and allergic reaction.

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 "**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 REVATIO.

5. How to store REVATIO

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package.
- Keep the blister strip in the outer carton.
- Protect from light/moisture.
- Do not store in a bathroom.
- 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 REVATIO contains

- The active substance is sildenafil. Each tablet contains 20 mg of sildenafil.
- The other ingredients are calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose. The film coat contains glycerol triacetate, hypromellose, lactose monohydrate, titanium dioxide (E171).

What REVATIO looks like and contents of the pack

White to off-white round biconvex film-coated tablets debossed with ‘RVT 20’ on one side and ‘VLE’ on the other.

Transparent clear PVC/aluminium blister packs of 90 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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