

1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

STENDRIL 25 mg film coated tablets

STENDRIL 50 mg film coated tablets

STENDRIL 100 mg film coated tablets

Sildenafil 25 mg or 50 mg or 100 mg film coated tablets

Contains sugar

25 mg tablet: lactose 1,89 mg

50 mg tablet: lactose 3,78 mg

100 mg tablet: lactose 7,56 mg

Read all of this leaflet carefully before you start taking **STENDRIL**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **STENDRIL** 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 **STENDRIL** is and what it is used for
2. What you need to know before you take **STENDRIL**
3. How to take **STENDRIL**
4. Possible side effects
- 5 How to store **STENDRIL**
6. Contents of the pack and other information

1. What **STENDRIL** is and what it is used for

STENDRIL contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors. It works by helping to relax the blood vessels in your

penis, allowing blood to flow into your penis when you get sexually excited. **STENDRIL** will only help you to get an erection if you are sexually stimulated.

STENDRIL is a treatment for adult men with erectile dysfunction, sometimes known as impotence.

This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. What you need to know before you take **STENDRIL**

Do not take **STENDRIL** if you:

- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- If you are using cimetidine (used to treat ulcers), ketoconazole or itraconazole (used to treat fungal infections), erythromycin or rifampicin (used to treat infections) or ritonavir or saquinavir (used to treat HIV infections)
- if you are taking riociguat, a medicine used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). When taken with **STENDRIL**, the blood pressure lowering effects of riociguat are increased, if you are taking riociguat, or are unsure, talk to your doctor.
- if you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION), a medical condition where the optic nerve is damaged due to loss of blood supply
- if you have certain rare inherited eye diseases (such as retinitis pigmentosa)
- If you have a severe liver or kidney problem.

Warnings and precautions

Talk to your doctor before taking **STENDRIL**.

- **If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.**

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie's Disease.
- If you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking **STENDRIL** and contact your doctor immediately.
- You should not use **STENDRIL** with any other oral or local treatments for erectile dysfunction.
- You should not use **STENDRIL** with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.
- You should not take **STENDRIL** if you do not have erectile dysfunction.
- You should not take **STENDRIL** if you are a woman.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

STENDRIL should not be given to individuals under the age of 18.

Other medicines and STENDRIL

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

STENDRIL tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken **STENDRIL** and when you did.

Do not take **STENDRIL** with other medicines unless your doctor tells you that you can.

You should not take **STENDRIL** if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor,

pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take **STENDRIL** if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall in your blood pressure.

Tell your doctor or pharmacist if you are taking riociguat (refer section 2).

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of **STENDRIL**.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking **STENDRIL** with alpha-blockers. This is most likely to happen within 4 hours after taking **STENDRIL**. In order to reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start **STENDRIL**. Your doctor may start you on a lower dose (25 mg) of **STENDRIL**.

STENDRIL with food, drink and alcohol

STENDRIL can be taken with or without food. However, you may find that **STENDRIL** takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking **STENDRIL**.

Pregnancy and breastfeeding

STENDRIL is not indicated for use by women.

Driving and using machines

Some men taking **STENDRIL** in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

STENDRIL contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking **STENDRIL**.

3. How to take STENDRIL

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

Always take **STENDRIL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The usual oral dose is 50 mg taken as needed once daily.

*You should not take **STENDRIL** more than once a day.*

You should take **STENDRIL** about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you feel that the effect of **STENDRIL** is too strong or too weak, talk to your doctor or pharmacist.

STENDRIL will only help you to get an erection if you are sexually stimulated. The amount of time **STENDRIL** takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that **STENDRIL** takes longer to work if you take it with a heavy meal.

If **STENDRIL** does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

If you take more STENDRIL than you should

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist

4. Possible side effects

STENDRIL can have side effects.

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

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

- An allergic reaction

Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Serious skin reactions

Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.

These are all very serious side effects. If you have them, you may have had a serious reaction to STENDRIL. 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 pains. If this occurs during or after intercourse
 - Get in a semi-sitting position and try to relax.
 - Do not use nitrates to treat your chest pain.
- Prolonged and sometimes painful erections
- A sudden decrease or loss of vision
- Seizures or fits

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:

Headache.

Nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

Less Frequent side effects:

Vomiting, skin rash, eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), , presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

Frequency unknown:

Fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, retinal detachment, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note most but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to **STENDRIL**.

Reporting of side effects

If you get any 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 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 **STENDRIL**

5. How to store STENDRIL

Store all medicines out of reach of children.

Store at or below 25⁰ C

Store in the original package in order to protect from moisture

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6. Contents of the pack and other information

What STENDRIL contains

- The active substance is sildenafil
- The other ingredients are:
 - *Tablet core:* microcrystalline cellulose, Silica, Colloidal Anhydrous, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate
 - *Film coat:* Hydroxypropylmethyl cellulose, titanium dioxide, lactose monohydrate, triacetin, indigo carmine aluminium lake

What STENDRIL looks like and contents of the pack

STENDRIL 25 mg: Pale blue to blue, round film-coated tablet, debossed with '25' on one side and 'SL' on other side.

STENDRIL 50 mg: Pale blue to blue, capsule shaped film-coated tablets, debossed with 'SL50' on one side and plain on the other side.

STENDRIL 100 mg: Pale blue to blue, capsule shaped film-coated tablets, debossed with 'SL100' on one side and plain on the other side.

STENDRIL 25, 50 and 100 mg is available in blister packs in cartons of 2, 4, 8 or 12, 28 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

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