Approved Patient Information Leaflet for Medicines for Human Use: [PRODUCT NAME]

SCHEDULING STATUS:

S4

[PRODUCT NAME] 5 mg

[PRODUCT NAME] 10 mg

[PRODUCT NAME] 20 mg

Tadalafil

Contains sugar (lactose monohydrate)

Each 5 mg film-coated tablet contains 124,67 mg of lactose monohydrate.

Each 10 mg film-coated tablet contains 178,91 mg of lactose monohydrate.

Each 20 mg film-coated tablet contains 252,52 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking [PRODUCT NAME] because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

2. What you need to know before you take [PRODUCT NAME]

3. How to take [PRODUCT NAME]

4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

[PRODUCT NAME] contains the active substance tadalafil.

[PRODUCT NAME] is a treatment for men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

Tadalafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Following sexual stimulation tadalafil works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is an improved erection. Tadalafil will not help you if you do not have erectile dysfunction. It is important to note that tadalafil for the treatment of erectile dysfunction does not work if there is no sexual stimulation. You and your partner will need to engage in foreplay, just as you would if you were not taking any medicines for erectile dysfunction.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]:

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of [PRODUCT NAME]
- if you are taking any form of a group of medicines called nitrates. These are used in the treatment of angina
- if you have serious heart disease or recently had a heart attack within the last 90 days
- if you have recently had a stroke within the last 6 months

- if you have severe hepatic (liver) insufficiency (Child-Pugh Class C)
- if you have uncontrolled low or high blood pressure
- if you have ever had loss of vision because of a condition called non-arteritic anterior ischaemic optic neuropathy (NAION), also described as “stroke of the eye”. This may or may not have been connected to taking a medicine like tadalafil
- if you have previously experienced loss of hearing in one or both ears, with or without symptoms like vertigo and dizziness.

Warnings and precautions

Tell your doctor if you have a history of heart disease. Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart.

Take special care with [PRODUCT NAME]:

- if you are taking medicines to control your blood pressure as the dosage of these medicines might have to be adjusted to prevent your blood pressure from dropping too low
- if you notice any symptoms or feel any discomfort when you begin sexual activity, stop immediately and report the incident to your doctor
- and let your doctor know immediately If you experience sudden loss of vision or any change in vision
- and let your doctor know immediately if you experience a sudden loss of hearing or decrease in ability to hear. You may experience dizziness and ringing in your ears with this loss of hearing
- if you have kidney or liver disease

- if you experience prolonged erections (4 hours or more) while taking tadalafil. If this is not treated immediately it can lead to permanent damage and loss of potency
- if you have any malformations of the penis
- if you suffer from a type of anaemia called sickle cell anaemia or any type of cancer
- if you are taking other medication for erectile dysfunction as [PRODUCT NAME] should not be taken with certain other medicines (see section "Other medicines and PRODUCT NAME" below).

It is not known if [PRODUCT NAME] is effective in patients who have had:

- pelvic surgery
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy).

Children and adolescents

[PRODUCT NAME] is not intended for use by children and adolescents under the age of 18.

Other medicines and [PRODUCT NAME]

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

Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- medicines to control your blood pressure
- ketoconazole, itraconazole (used to treat fungal infections)
- rifampicin (used to treat tuberculosis)
- medicines used for the treatment and control of seizures (fits)
- ritonavir, saquinavir (used in the treatment of HIV/AIDS)
- antacids (used to neutralise acid in the stomach).

[PRODUCT NAME] with drink and alcohol

[PRODUCT NAME] may be taken with or without food.

Grapefruit juice may affect how well [PRODUCT NAME] will work and should be taken with caution.

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take [PRODUCT NAME], avoid excessive drinking (blood alcohol level of 0,08 % or greater), since this may increase the risk of dizziness when standing up.

Pregnancy, breastfeeding and fertility

- [PRODUCT NAME] is not intended for use by women. If you and your partner are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking [PRODUCT NAME]
- you should not use this medicine during pregnancy

- you should not breastfeed while using [PRODUCT NAME].

Driving and using machines

- you may experience dizziness while using [PRODUCT NAME]
- it is not always possible to predict to what extent [PRODUCT NAME] 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 [PRODUCT NAME] affects them.

[PRODUCT NAME] contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking [PRODUCT NAME].

[PRODUCT NAME] contains sodium

[PRODUCT NAME] contains less than 1 mmol sodium (23 mg) per film-coated tablet, i.e. is essentially “sodium-free”.

3. How to take [PRODUCT NAME]

Do not share medicines prescribed for you with any other person.
Always take [PRODUCT NAME] exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- the usual dose is 5 mg daily at approximately the same time of the day.
- the maximum dose is 20 mg a day.
- you should not take [PRODUCT NAME] more than once in a day.
- [PRODUCT NAME] may be taken up to 36 hours or as early as 16 minutes prior to when you want to engage in sexual activity.
- swallow the tablet whole with a glass of water.

If you have the impression that the effect of [PRODUCT NAME] is too strong or too weak, tell your doctor or pharmacist.

If you take more [PRODUCT NAME] than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You may experience headache, discomfort in your stomach, back or muscle pain and an erection that lasts longer than 4 hours.

If you forget to take [PRODUCT NAME]

If you forget to take [PRODUCT NAME], take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

[PRODUCT NAME] can have side effects.

Not all side effects reported for [PRODUCT NAME] are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking [PRODUCT NAME], please consult your doctor, pharmacist or other healthcare professional for advice. If any of the following happens, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty breathing
- severe skin rash or itching
- swollen tongue or lips.

These are all very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. 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
- an erection that lasts longer than 4 hours
- sudden loss of vision

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
- reddening of the face (flushing)
- stuffy nose
- discomfort in your stomach
- back pain, pain in your muscles or any part of your body.

Less frequent side effects:

- dizziness
- loss of consciousness or numbness on one side of the body
- fainting, severe headache (migraine), sudden memory loss
- blurred vision or loss of vision, eye pain, swelling of eyelids, redness or itching of the eye
- ringing in ears, loss of hearing
- changes in heart rhythm, chest pain or feeling of pressure in chest
- low or high blood pressure
- difficulty breathing, nose bleeds

- stomach pain, nausea, vomiting, heartburn or burning sensation in your throat
- rash, sweating
- blood in urine
- prolonged erections, blood in the sperm or bleeding from the penis
- chest pain, tiredness, swelling of the legs or face.

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. 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 [PRODUCT NAME]**.**

5. How to store [PRODUCT NAME]

- Store all medicines out of reach and sight of children.
- Store at or below 30 °C.
- Store in the original package.
- Keep the blisters in the outer carton.
- There are no special storage instructions for [PRODUCT NAME].
- Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.
- 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 [PRODUCT NAME] contains

The active substance is tadalafil. Each tablet contains 5 mg,10 mg or 20 mg of tadalafil.

The other ingredients are:

Tablet core: lactose monohydrate, pregelatinised starch, colloidal anhydrous silica, croscarmellose sodium, sodium laurilsulfate, magnesium stearate.

Film-coat: hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, talc (E553b), iron oxide yellow (E172), iron oxide red (E172).

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 5 mg is a pale yellow, oval shape, film-coated tablet, debossed with ‘5’ on one side and plain on the other side.

[PRODUCT NAME] 10 mg is a pale yellow, oval shaped, film-coated tablet, debossed with ‘10’ on one side and plain on the other side.

[PRODUCT NAME] 20 mg is a pale yellow, oval shape, film-coated tablet, debossed with ‘20’ on one side and plain on the other side.

[PRODUCT NAME] 5 mg film-coated tablets are packaged in PVC/PCTFE/Aluminium blisters in pack sizes of 4, 14, 28 and 30 film-coated tablets in carton boxes. Not all pack sizes may be marketed.

[PRODUCT NAME] 10 mg film-coated tablets are packaged in PVC/PCTFE/Aluminium blisters in pack sizes of 4, 8 and 12 film-coated tablets in carton boxes. Not all pack sizes may be marketed.

[PRODUCT NAME] 20 mg film-coated tablets are packaged in PVC/PCTFE/Aluminium blisters in pack sizes of 2, 4, 8 and 12 film-coated tablets in carton boxes. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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TELDESEL 5 mg film-coated tablets: 51/7.1.5/0279

TELDESEL 10 mg film-coated tablets: 51/7.1.5/0280

TELDESEL 20 mg film-coated tablets: 51/7.1.5/0281

TADALAFIL 5 mg AUSTELL film-coated tablets: 51/7.1.5/0282.279

TADALAFIL 10 mg AUSTELL film-coated tablets: 51/7.1.5/0283.280

TADALAFIL 20 mg AUSTELL film-coated tablets: 51/7.1.5/0284.281