PATIENT INFORMATION LEAFLET – TADALAFIL

SCHEDULING STATUS: S4

TIDALIS 5, 5 mg film-coated tablets.

TIDALIS 20, 20 mg film-coated tablets.

Tadalafil

Contains lactose:

Each **5** mg film coated tablet contains 81,7 mg lactose (as monohydrate).

Each **20** mg film coated tablet contains 326.8 mg lactose (as monohydrate).

Each 5 mg film coated tablet contains 0.02 mmol (0.55 mg) sodium.

Each 20 mg film coated tablet contains 0.09 mmol (2.20 mg) sodium.

Read all of this leaflet carefully before you start taking TIDALIS

- 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.
- **TIDALIS** 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 **TIDALIS** is and what it is used for
2. What you need to know before you take **TIDALIS**
3. How to take **TIDALIS**
4. Possible side effects
5. How to store **TIDALIS**

6. Contents of the pack and other information

1. What TIDALIS is and what it is used for

TIDALIS contains the active substance tadalafil.

TIDALIS is a treatment for men with erectile disfunction. 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 TIDALIS

Do not take TIDALIS:

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of **TIDALIS** (listed in section 6.1)
- 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.
- recently had a stroke within the last 6 months
- have low blood pressure or uncontrolled high blood pressure.
- Have a severe hepatic (liver) insufficiency (Child-Pugh Class C).
- If you have ever had loss of vision because of a condition called non-arteritic anterior

ischemic 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 **TIDALIS**:

- 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 have experienced the following:
    - a heart attack in the last 90 days
    - angina (a chest pain which feels like pressure or squeezing in your chest) during sexual intercourse
    - heart failure in the last 6 months
    - uncontrolled low or high blood pressure or a problem with the rhythm of your heartbeat
    - a stroke in the last 6 months
- 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 **TIDALIS** should not be taken with certain other medicines (see section “Other medicines and **TIDALIS**” below).

It is unknown if **TIDALIS** 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 nonnerve-sparing prostatectomy).

Children and adolescents

TIDALIS is not intended for use by children and adolescents under the age of 18.

Other medicines and **TIDALIS**

- 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)

TIDALIS with food and drink

- **TIDALIS** may be taken with or without food.
- Grapefruit juice may affect how well **TIDALIS** 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 **TIDALIS**, 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

- **TIDALIS** is not indicated for use in 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 this medicine.
- You should not use this medicine during pregnancy.
- You should not breast-feed while using **TIDALIS**.

Driving and using machines

- You may experience dizziness while using **TIDALIS**.
- It is not always possible to predict to what extent **TIDALIS** 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 **TIDALIS** affects them.

TIDALIS contains lactose monohydrate:

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

TIDALIS contains salts (sodium):

TIDALIS 5 & 20 contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium free’.

3. How to take TIDALIS

- Do not share medicines prescribed for you with any other person.
- Always take **TIDALIS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day.
- The maximum dose is 20 mg a day.
- You should not take **TIDALIS** more than once in a day.
- **TIDALIS** 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 **TIDALIS** is too strong or too weak, tell your doctor or pharmacist.

If you take more TIDALIS than you should

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

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 TIDALIS

If you forget to take **TIDALIS**, take it as soon as you remember. Do not take a double dose to make up for forgotten doses.

4. Possible side effects

- **TIDALIS** can have side effects.
- Not all side effects reported for **TIDALIS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TIDALIS**, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking **TIDALIS** 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 **TIDALIS**. 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, pharmacist or nurse. 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 **TIDALIS**.

5. How to store TIDALIS

- Keep out of reach and sight of children.
- Store at or below 25 °C in the original carton until removed for use.
- Protect from moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What TIDALIS contains

Each film coated tablet contains 5 mg or 20 mg tadalafil.

The other ingredients are colloidal silicone dioxide, croscarmellose sodium, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, methanol, methylene chloride, opadry yellow, povidone, sodium lauryl sulphate.

TIDALIS contains: Sugar (lactose).

What TIDALIS looks like and contents of the pack

TIDALIS 5 mg: Yellow to light yellow, round shaped, bevelled edge, coated tablets debossed with ‘L 337’ on one side and plain on the other side.

TIDALIS 20 mg: Yellow to light yellow, round shaped, bevelled edge, coated tablets debossed with ‘L 339’ on one side and plain on the other side.

TIDALIS tablets 5 mg and 20 mg are both available in Blister pack of unprinted aluminum foil and unprinted CFB foil and blister pack of unprinted aluminum foil and clear PVC/Alcar film of 2, 4, 8 or 10 tablets per strip in printed unit carton.

HOLDER OF CERTIFICATE OF REGISTRATION

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South Africa

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Will be allocated by SAHPRA upon registration.

Registration number

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