

Product Name: TADALAFIL UNICORN 2.5/5/20
Applicant: Unicorn Pharmaceuticals (Pty) Ltd

SAHPRA PV safety concern:
Risk of retinal detachment with
the use of phosphodiesterase 5
inhibitors.

PATIENT INFORMATION LEAFLET FOR TADALAFIL UNICORN

SCHEDULING STATUS

S4

TADALAFIL 2,5 UNICORN (2,5 mg, tablets)

TADALAFIL 5 UNICORN (5 mg, tablets)

TADALAFIL 20UNICORN (20 mg, tablets)

Each TADALAFIL 2,5 UNICORN film coated tablet contains 2,5 mg tadalafil.

Contains sugar (lactose monohydrate 80,625 mg/tablet).

Each TADALAFIL 5 UNICORN film coated tablet contains 5 mg tadalafil

Contains sugar lactose monohydrate 78,125 mg/tablet).

Each TADALAFIL 20 UNICORN film coated tablet contains 20 mg tadalafil.

Contains sugar (lactose monohydrate 312,5 mg/tablet).

Read all of this leaflet carefully before you start taking TADALAFIL UNICORN

- 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.
- **TADALAFIL UNICORN** 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.

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What is in this leaflet

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

1. What TADALAFIL UNICORN is and what it is used for

TADALAFIL UNICORN contains the active substance tadalafil.

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 TADALAFIL UNICORN

Do not take TADALAFIL UNICORN:

- if you are hypersensitive (allergic) to tadalafil or any of the other ingredients of **TADALAFIL UNICORN** (listed in section 6.1)

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- if you are taking any form of a group of medicines called nitrates. These are used in the treatment of angina.
- if you have severe liver disease.
- 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 **TADALAFIL UNICORN**:

- 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

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- 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 **TADALAFIL UNICORN** should not be taken with certain other medicines (see section “Other medicines and **TADALAFIL UNICORN**’ below).

Other medicines and TADALAFIL UNICORN

- 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

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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).

TADALAFIL UNICORN with food and drink

- **TADALAFIL UNICORN** may be taken with or without food.

Pregnancy, breastfeeding and fertility

- **TADALAFIL UNICORN** 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 **TADALAFIL UNICORN**.

Driving and using machines

- You may experience dizziness while using **TADALAFIL UNICORN**.
- It is not always possible to predict to what extent **TADALAFIL UNICORN** may interfere with the daily activities of a patient.

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Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **TADALAFIL UNICORN** affects them.

TADALAFIL UNICORN 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 TADALAFIL UNICORN

- Do not share medicines prescribed for you with any other person.
- Always take **TADALAFIL UNICORN** exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.
- The usual dose is 2,5 mg to 5 mg daily.
- The maximum dose is 20 mg a day.
- You should not take **TADALAFIL UNICORN** more than once in a day.
- **TADALAFIL UNICORN** 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 **TADALAFIL UNICORN** is too strong or too weak, tell your doctor or pharmacist.

If you take more TADALAFIL UNICORN 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,

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back or muscle pain and an erection that lasts longer than 4 hours.

If you forget to take TADALAFIL UNICORN

If you forget to take **TADALAFIL UNICORN**, take it as soon as you remember. Do not take a double dose to make up for forgotten doses. You should not take **TADALAFIL UNICORN** more than once in a day.

4. Possible side effects

TADALAFIL UNICORN can have side effects.

Not all side effects reported for **TADALAFIL UNICORN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TADALAFIL UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **TADALAFIL UNICORN** 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 **TADALAFIL UNICORN**. 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:

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- Chest pain
- An erection that lasts longer than 4 hours
- Sudden loss of vision.
- Retinal Detachment – When small dark spots or wavy lines float across your vision, flash of light in one or both eyes, a dark shadow or “curtain” on the sides or in the middle of your field 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

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- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Adverse reactions can also be reported directly to Unicorn Pharmaceuticals (Pty) Ltd at vigilance@unicompharma.co.za. By reporting side effects, you can help provide more information on the safety of **TADALAFIL UNICORN**.

5. How to store TADALAFIL UNICORN

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep blister strips in the carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date stated on the carton.

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- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TADALAFIL UNICORN contains

Each film coated tablet contains 2,5 mg, 5 mg or 20 mg tadalafil.

The other ingredients are: anhydrous lactose, croscarmellose sodium, hydroxypropylcellulose, hypromellose 2910 (E464), iron oxide yellow (E172), lactose monohydrate, magnesium stearate, polysorbate 80, sodium laurilsulfate, talc, titanium dioxide (E171) and triacetin.

In addition, **TADALAFIL 2,5 UNICORN** contains iron oxide red (E172).

What TADALAFIL UNICORN looks like and contents of the pack

TADALAFIL 2,5 UNICORN: A yellow-orange coloured, caplet shaped, biconvex, film-coated tablet, debossed with “T 2” on one side and plain on the other.

TADALAFIL 5 UNICORN: A yellow coloured, caplet shaped, biconvex, film-coated tablet, debossed with “T 5” on one side and plain on the other.

TADALAFIL 20 UNICORN: A yellow coloured, caplet shaped, biconvex, film-coated tablet, debossed with “T 20” on one side and plain on the other.

TADALAFIL UNICORN film-coated tablets are packed in blister strips consisting of aluminium foil and clear PVC/PVDC film packed into a cardboard box.

Pack sizes:

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TADALAFIL 2,5 UNICORN: 28 film-coated tablets.

TADALAFIL 5 UNICORN: 28 film-coated tablets.

TADALAFIL 20 UNICORN: 2 & 4 film-coated tablets.

HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Cnr. Searle & Pontac Streets

Woodstock, Cape Town

South Africa

8001

This leaflet was last revised in

07 June 2024

Registration number

TADALAFIL 2,5 UNICORN: A52/7.1.5/0468

TADALAFIL 5 UNICORN: A52/7.1.5/0469

TADALAFIL 20 UNICORN: A52/7.1.5/0470