TALEGRIA 5 and TALEGRIA 20

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TALEGRIA 5 mg film-coated tablet

TALEGRIA 20 mg film-coated tablet

Tadalafil

Contains sugar:

Each 5 mg film-coated tablet contains 57,5 mg lactose (as monohydrate).

Each 20 mg film-coated tablet contains 230 mg lactose (as monohydrate)

Read all of this leaflet carefully before you start taking TALEGRIA

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

1. What TALEGRIA is and what it is used for

TALEGRIA contains the active substance tadalafil. Tadalafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors. TALEGRIA 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.
Following sexual stimulation, TALEGRIA 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. TALEGRIA 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 TALEGRIA

Do not take TALEGRIA:

- If you are hypersensitive (allergic) to tadalafil or any of the other ingredients of TALEGRIA (listed in section 6).
- 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 recently had a stroke within the last 6 months.
- If you have low blood pressure or uncontrolled high blood pressure.
- If you 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 TALEGRIA.
- 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 TALEGRIA:

- 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 TALEGRIA should not be taken with certain other medicines (see section “Other medicines and TALEGRIA” below).

It is not known if TALEGRIA 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

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

Other medicines and TALEGRIA

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

TALEGRIA with food, drink and alcohol

Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take TALEGRIA, avoid excessive drinking, since this may increase the risk of dizziness when standing up.

TALEGRIA may be taken with or without food.

Grapefruit juice may affect how well TALEGRIA will work and should be taken with caution.

Pregnancy, breastfeeding and fertility

- TALEGRIA 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 TALEGRIA.
- You should not use TALEGRIA during pregnancy.
- You should not breastfeed while using TALEGRIA.

Driving and using machines

You may experience dizziness while using TALEGRIA.

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

TALEGRIA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking TALEGRIA.

TALEGRIA contains sodium

TALEGRIA contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take TALEGRIA

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

Always take TALEGRIA exactly as your doctor 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 TALEGRIA more than once in a day.

TALEGRIA 20 mg 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 TALEGRIA is too strong or too weak, tell your doctor or pharmacist.

If you take more TALEGRIA 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 TALEGRIA

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

4. Possible side effects

TALEGRIA can have side effects.

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

If any of the following happens, stop taking TALEGRIA 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 TALEGRIA. 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;
- 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. 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 TALEGRIA.

5. How to store TALEGRIA

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the blister or carton.
- 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 TALEGRIA contains

The active substance is tadalafil.

Each TALEGRIA 5 film-coated tablet contains 5 mg tadalafil.

Each TALEGRIA 20 film-coated tablet contains 20 mg tadalafil.

The other ingredients are croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), Opadry Yellow (coating, containing hypromellose (E464(i)), iron oxide yellow (E172), lactose monohydrate, talc (E553b), titanium dioxide (E171)), triacetin).

What TALEGRIA looks like and contents of the pack

TALEGRIA 5: Yellow coloured, oval shape, biconvex with bevel edge, film-coated tablets debossed '897' on one side and plain on the other side.

TALEGRIA 20: Yellow coloured, oval shape, biconvex with bevel edge, film-coated tablets debossed '899' on one side and plain on the other side.

Clear PVC/PVDC and aluminium blister strips placed in an outer carton.

Pack size:

TALEGRIA 5*:* 28 tablets.

TALEGRIA 20: 2, 4 and 8 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

Tel: 012 748 6400

This leaflet was last revised in:

13 September 2022.

Registration numbers

TALEGRIA 5: 49/7.1.5/1196

TALEGRIA 20: 49/7.1.5/1197