PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CIALIS, 20 mg, film-coated tablets

Tadalafil

Contains sugar: lactose 233 mg (as monohydrate)

Read all of this leaflet carefully before you start taking CIALIS

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

1. What CIALIS is and what it is used for

CIALIS contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

CIALIS is a treatment for adult men with erectile dysfunction: This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

It is important to note that CIALIS does not work if there is no sexual stimulation.

2. What you need to know before you take CIALIS

Do not take CIALIS if you:

- are hypersensitive (allergic) to tadalafil or any of the other ingredients of CIALIS (listed in section 6).
- are taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines (nitrates) used in the treatment of angina pectoris (chest pain). CIALIS has been shown to increase the effects of these medicines. If you are taking any form of nitrate, or are unsure, tell your doctor.
- have serious heart disease or had a heart attack.
- have chest pains during or after sexual activity, have abnormal heart rhythm or heart failure.
- had a stroke.
- have low blood pressure or uncontrolled high blood pressure.
- have a severe liver problem.
- If you are also using any of the following medicines: azole antifungals such as ketoconazole, itraconazole, voriconazole, ritonavir and other protease inhibitors.
- have had previous experience of a decrease or loss of hearing in one or both ears, with or without dizziness.
- have ever had an experience of partial, sudden, temporary or permanent decrease or loss of vision in one or both eyes.
- If you are taking any guanylate cyclase stimulators such as riociguat. This group of medicines is used to treat pulmonary hypertension. CIALIS used together with these medicines may cause low blood pressure.

Warnings and precautions

Take special care with CIALIS:

Sexual activity carries a possible risk if you have heart disease because it puts an extra strain on your heart. If you have a heart problem, you should tell your doctor.

In case of chest pain occurring during or after sexual activity you should NOT use nitrates, but you should seek immediate medical assistance.

If you experience long erections lasting 4 hours or more, talk to your doctor immediately as this can result in permanent tissue damage.

Before taking CIALIS, tell your doctor if you have:

- sickle cell anaemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukaemia (cancer of the blood cells).
- any deformation of your penis.
- a serious liver problem.

CIALIS is not intended for use by women or by children or adolescents under the age of 18.

Other medicines and CIALIS

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

This is particularly important if you are treated with nitrates for angina (chest pains), or use blood pressure-lowering medicines, as you should not take CIALIS if you are taking these medicines.

You should not use CIALIS together with any other treatments for erectile dysfunction.

Tell your doctor if you are using riociguat to treat pulmonary hypertension. CIALIS used together with this medicine may cause low blood pressure.

CIALIS with food, drink and alcohol

You may take CIALIS with or without food. Grapefruit juice may affect how well CIALIS will work and should be taken with caution.

Talk to your doctor for further information.

Pregnancy, breastfeeding and fertility

Cialis is not indicated for use by women.

Driving and using machines

You may experience dizziness while using CIALIS.

It is not always possible to predict to what extent CIALIS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CIALIS affects you.

CIALIS contains lactose

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

CIALIS contains sodium

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

3. How to take CIALIS

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

Always take CIALIS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is a 20 mg CIALIS (one tablet) before sexual activity.

CIALIS tablets are for oral use. Swallow the tablet whole with some water. You may take CIALIS with or without food.

You may take a CIALIS tablet at least 16 minutes before sexual activity. CIALIS may still be effective up to 36 hours after taking the tablet. It is important to note that CIALIS does not work if there is no sexual stimulation.

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

You should NOT take CIALIS more than once a day. CIALIS 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

Your doctor will tell you how long your treatment with CIALIS will last.

If you have the impression that the effect of CIALIS is too strong or too weak, tell your doctor or pharmacist.

If you take more CIALIS than you should

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

If you forget to take CIALIS

Do not take a double dose to make up for forgotten doses. If you have any further questions on the use of CIALIS, ask your doctor or pharmacist.

4. Possible side effects

CIALIS can have side effects.

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

If any of the following happens, stop taking CIALIS 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 CIALIS. 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 Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. Alternatively, report suspected adverse events to the company at ade_za@lilly.com. By reporting side effects, you can help provide more information on the safety of CIALIS.

5. How to store CIALIS

Store all medicines out of reach of children.

Store at or below 25 °C. Store in original package.

Do not use CIALIS after the expiry date stated on the carton and blister.

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 CIALIS contains

The active substance is tadalafil 20 mg.

The other ingredients are lactose monohydrate, croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurylsulphate, magnesium stearate, hypromellose, triacetin, titanium dioxide (E171), iron oxide (E172), and talc.

What CIALIS looks like and contents of the pack

CIALIS tablets are yellow film-coated and almond shaped, marked 'C 20' on one side.

CIALIS is available as aluminium/PVC or aluminium/PVC/PE/PCTFE blister strips packed in cartons of 2, 4 or 8 tablets.

Holder of Certificate of Registration

Eli Lilly (S.A.) (Pty) Limited

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