

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CIALIS 5 film-coated tablets

Tadalafil

Contains sugar: lactose 121 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.

CIALIS 5 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.

CIALIS 5 is also used to treat

- Benign prostatic hyperplasia (BPH) - BPH means that the prostate has become enlarged and it is not cancerous.

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 6.1).
- 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 have had a heart attack.
- have had a stroke.
- have low blood pressure or uncontrolled high blood pressure.
- have a severe kidney problem.
- 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.
- 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.
- a severe kidney 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.

Do not take CIALIS more than once a day.

For the treatment of erectile dysfunction: The recommended dose is 5 mg tablet taken once a day at approximately the same time of the day.

Your doctor may adjust the dose based on your response to CIALIS.

For the treatment benign prostatic hyperplasia: The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day.

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

When taken once a day, CIALIS allows you to obtain an erection, when sexually stimulated, at any time point during the next 24 hours of the day.

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.

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.

Paediatric population

CIALIS should not be used in children.

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.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. 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.

4. 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).

5. Contents of the pack and other information

What CIALIS contains

The active substance is tadalafil 5 mg in CIALIS 5.

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

What CIALIS looks like and contents of the pack

CIALIS 5 are film-coated, yellow, almond-shaped tablets debossed marked "C 5" on one side.

CIALIS 5 is available in aluminium/PVC/PE/PCTFE blisters, with a clear plastic web film, in cartons of 28 tablets. Each blister contains 14 tablets and there are two blisters per carton.

Holder of Certificate of Registration

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CIALIS 5
Tablets; 5 mg tadalafil

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