

Package leaflet: Information for the user
CIALIS 2.5 mg film-coated tablets
tadalafil

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

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1. What is CIALIS and what is it used for?

CIALIS is intended for the treatment of adult men with erectile dysfunction. This is due to the when a man cannot get an erection or cannot maintain an erection long enough that is suitable for sexual activity. CIALIS has been shown to significantly improve the ability to achieve an erection suitable for sexual activity.

CIALIS contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. After sexual stimulation, CIALIS helps relax the blood vessels in the penis, allowing blood to flow into your penis. This results in an improvement in your erection. CIALIS does not work if you do not have erectile dysfunction.

It is important to know that CIALIS does not work without sexual stimulation. You and your partner need to know that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to tadalafil or any of the other ingredients in this medicine. These ingredients can be found in section 6.
- You are using an organic nitrate in any form or a medicine that releases nitric oxide (such as amyl nitrite). This is a group of medicines (nitrates) used for the treatment of angina pectoris (chest pain). It has been shown that CIALIS enhances the effect of these

medicines. If you are using nitrate in any form or are unsure whether you are using it, tell your doctor.

- You have a serious heart condition or have had a heart attack in the last 90 days.
- You have had a stroke in the last 6 months.
- You have low blood pressure or high blood pressure that is not controlled.
- You have ever had loss of vision due to non-arteritic ischemic anterior optic neuropathy (NAION), a condition described as “paralysis of the eye”.
- You are using riociguat. This medication is used to treat pulmonary arterial hypertension (this is high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (this is high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as CIALIS, have been shown to increase the blood pressure-lowering effect of this medication. If you are using riociguat or are unsure, contact your doctor.

When should you be extra careful with this medicine?

Contact your doctor before using this medicine.

Be aware that sexual activity can be risky for patients with a heart condition because this activity requires extra effort from your heart. If you have a heart condition, tell your doctor.

Tell your doctor before taking the tablets if you have any of the following conditions:

- sickle cell anemia (a disorder of the red blood cells),
- multiple myeloma (bone marrow cancer),
- leukemia (blood cell cancer),
- a deformity of your penis,
- a severe liver problem,
- a severe kidney problem.

It is not known if CIALIS is effective in patients who

- have undergone pelvic surgery,
- complete or partial removal of the prostate gland, where the nerve pathways of the prostate have been severed (radical non-nerve-sparing prostatectomy), have undergone.

If you suddenly notice a reduction or loss of vision, or if your vision is distorted or blurred while using CIALIS, stop using CIALIS and contact your doctor immediately.

Sudden onset of reduced hearing or hearing loss has been observed after using tadalafil in some patients. Although it is not known if these cases are directly due to tadalafil, you should contact your doctor as soon as you notice sudden onset of reduced hearing or hearing loss. notes.

Children and adolescents under 18 years

CIALIS is not intended for use by children and adolescents under 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides CIALIS, have you done so recently, or is there a

possibility that you will soon take other medicines? Then tell your doctor. Do not take CIALIS if you are already taking nitrates.

Some medicines are affected by CIALIS or can affect how CIALIS works. Tell your doctor or pharmacist if you are already taking the following medicines: an alpha-blocker (used to treat high blood pressure or urinary problems associated with benign

- an alpha-blocker (used to treat high blood pressure or urinary symptoms associated with benign to treat prostatic hypertrophy),
- other medicines to treat high blood pressure,
- riociguat,
- a 5-alpha reductase inhibitor (used for the treatment of benign prostatic hyperplasia),
- medicines such as ketoconazole tablets (to treat a fungal infection) and protease inhibitors for the treatment of AIDS or HIV infection,
- phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures),
- rifampicin, erythromycin, clarithromycin, or itraconazole,
- other treatments for erectile dysfunction.

What should you be aware of with drinking and alcohol?

See section 3 for information on the effect of alcohol consumption. Grapefruit juice may affect how well CIALIS will work and should be taken with caution. Ask your doctor for more information about this.

Fertility

In treated dogs, there was reduced sperm production in the testes. A reduction in sperm has also been observed in some men. It is unlikely that these effects will lead to a lack of fertility.

Driving and using machines

Some men who took CIALIS in clinical studies reported dizziness. Carefully check how you react to the tablets before driving or operating machinery.

CIALIS contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

CIALIS contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Unsure about the correct usage? Then contact your doctor or pharmacist.

CIALIS tablets are intended for oral use by men only. Swallow the tablet whole with some water. You can take CIALIS with or without food.

The recommended dose is 5 mg once a day, taken at approximately the same time each day. Your doctor may adjust the dose to 2.5 mg depending on your response to CIALIS. This will be given as a 2.5 mg tablet. Do not take CIALIS more than once a day.

Using CIALIS once a day can be beneficial for men who expect to be sexually active twice a week or more often.

When you take CIALIS once a day, you are able to get an erection at any time during the 24 hours of the day when you are sexually stimulated. It is important to know that CIALIS does not work without sexual stimulation. You and your partner should know that foreplay is necessary, just as you would if you were not taking medication for erectile dysfunction.

Drinking alcohol can affect your ability to get an erection and can temporarily lower your blood pressure. If you have taken CIALIS or are planning to take CIALIS, avoid excessive drinking (blood alcohol level 0.08% or higher), as this can increase the risk of dizziness when standing up.

Have you used too much of this medicine?

Inform your doctor. You may experience side effects as described in section 4.

Have you forgotten to use this medicine?

Take your dose as soon as you remember, but do not take a double dose to make up for a missed tablet. You should not take CIALIS more than once a day.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These side effects are usually mild to moderate in nature.

If you experience any of the following side effects, stop taking CIALIS and seek immediate medical help:

- Allergic reactions including rash (occurs sometimes).
- Chest pain - do not use nitrates but seek immediate medical help (occurs sometimes).
- Priapism, a prolonged and possibly painful erection after taking CIALIS (rarely occurs for). If you have such an erection and it lasts longer than 4 hours, contact your doctor immediately. your doctor.
- You suddenly cannot see (rare), distorted, blurred, hazy central vision or sudden decreased vision (frequency not known).

Other reported side effects include:

Common (occur in less than 1 in 10 patients)

- headache, back pain, muscle pain, pain in arms and legs, facial flushing, nasal congestion and digestive problems.

Uncommon (occur in less than 1 in 100 patients)

- dizziness, abdominal pain, nausea (vomiting), reflux, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, palpitations, a rapid heartbeat, high blood pressure, low blood pressure, nosebleeds, tinnitus, swelling of the hands, feet or ankles and feeling tired.

Rare (occur in less than 1 in 1000 patients)

- fainting, seizures and transient memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the skin surface), bleeding from the penis, presence of blood in the semen and increased sweating.

A heart attack and stroke have also been rarely reported in men taking CIALIS. Most of those men had pre-existing heart problems before taking this medication.

There have rarely been reports of partial, temporary, or permanent decrease or loss of vision in one or both eyes.

Some other side effects that rarely occurred in men taking CIALIS and were not seen during clinical trials include:

- migraine, swollen face, severe allergic reaction causing the face and throat to swell, severe skin rash, certain disorders related to blood supply to the eyes, irregular heartbeat, angina, and sudden cardiac death.
- distorted, blurred, hazy central vision or sudden decrease in vision (frequency not known).

The side effect dizziness is more frequently reported in men over 75 years using CIALIS. Diarrhea is more frequently reported in men over 65 years using CIALIS.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find it on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect against moisture. Store below 30°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. If you dispose of medicines in the correct way, they are destroyed responsibly and do not end up in the environment. right.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is tadalafil. Each tablet contains 2.5 mg tadalafil.
- The other substances in this medicine are:
Tablet core: lactose monohydrate (see end of section 2), croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate, see section 2 "CIALIS contains lactose". Film coating: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), talc.

What does CIALIS look like and what is in a package?

CIALIS 2.5 mg is a light orange-yellow almond-shaped film-coated tablet and is marked on one side with "C 2½".

CIALIS 2.5 mg is available in blister packs of 28 tablets.

Marketing authorization holder and manufacturer

Marketing authorization holder: Eli Lilly Nederland B.V, Papendorpseweg 83, 3528 BJ Utrecht, Netherlands

Manufacturer: Lilly S.A., Avda. de la Industria 30, 28108 Alcobendas, Madrid, Spain.

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More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>.

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