

Package leaflet: Information for the user
CIALIS 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? 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 that is not listed in this leaflet? Then contact your doctor or pharmacist.

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

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

CIALIS 5 mg is used for the treatment of men with:

- erectile dysfunction. This occurs when a man cannot get or maintain an erection long enough for sexual activity. It has been shown that CIALIS significantly improves the ability to achieve an erection suitable for sexual activity. improves. 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 for the treatment of erectile dysfunction does not work without sexual stimulation. You and your partner should know that foreplay is necessary, just as you would if you were not using a medication for urinary symptoms associated with a common condition
- called benign prostatic hyperplasia. This means that the prostate gland enlarges with age. Symptoms include difficulty urinating, feeling like the bladder is not completely empty after urination, and needing to urinate more frequently, including at night. CIALIS improves blood flow to the prostate and bladder and relaxes the muscles in these areas; this can reduce the symptoms of benign prostatic hyperplasia. It has been shown that CIALIS reduces these urinary symptoms within 1 to 2 weeks after starting treatment. symptoms of benign prostatic hyperplasia reduce. It has been shown that CIALIS this symptoms in the urinary tract within 1 to 2 weeks after the start of treatment improves.

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

When should you not use this medicine?

- You are allergic to tadalafil or any of the other ingredients in this medicine. You can find these ingredients 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 nerve disorder (NAION), a condition described as “paralysis of the eye.”
- You use riociguat. This medicine 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 medicine. 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.

Because benign prostatic hyperplasia and prostate cancer can have the same symptoms, your doctor will check you for prostate cancer before starting treatment with CIALIS for benign prostatic hyperplasia. CIALIS is not used for the treatment of prostate cancer.

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

- 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 decrease 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 decreased hearing or hearing loss has been observed in some patients after using tadalafil. 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 decreased hearing or hearing loss.

Children and adolescents under 18 years

CIALIS is not intended for use by children and adolescents under 18 years.
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Are you using any other medicines?

Are you using any other medicines besides CIALIS, have you done so recently, or is there a possibility that you will use other medicines soon? 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 symptoms associated with benign prostatic hyperplasia),
- other medicines to treat high blood pressure,
- riociguat,
- a 5-alpha reductase inhibitor (used to treat benign prostatic hyperplasia), medicines such as ketoconazole tablets (used to treat fungal infections) and protease inhibitors for the treatment of AIDS or HIV infection,
- phenobarbital, phenytoin, and carbamazepine (medicines used 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 effects 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 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 have an intolerance to some sugars, contact your doctor before taking this medicine.

CIALIS contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, meaning 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 use? 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.

Drinking alcohol can temporarily lower your blood pressure. If you have taken CIALIS or if you plan to take CIALIS, avoid excessive drinking (blood alcohol level 0.08% or higher), as this may increase the risk of dizziness when standing up.

For the treatment of erectile dysfunction

The recommended dosage is 5 mg taken once daily 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.

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 sexually stimulated. Using CIALIS once a day can be useful for men who expect to be sexually active two or more times a week. 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. use.

The dose is one 5 mg tablet taken once daily at approximately the same time of day.

If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet per day.

Do not take CIALIS more than once a day. Have you used too much of this medicine?

Do not take CIALIS more than once a day.

Have you used too much of this medicine?

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

Did you forget to use this medicine?

Take your dose as soon as you remember, but do not take a double dose to make up for a forgotten 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 any medicine, this medicine can have side effects, although not everyone 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

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

- Allergic reaction 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). If you have such an erection and it lasts longer than 4 hours, contact your doctor immediately. You
- suddenly cannot see (rarely occurs), 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

- headache digestive problems. Sometimes (occur in less than 1 in 100 patients)

dizziness

- dizziness eye pain, difficulty, difficulty with breathing, presence of blood in the urine, prolonged erection, palpitations, a rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, 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 eyes, 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 already had heart problems before taking this medication.

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

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

- migraine, swollen face, severe allergic reaction causing swelling of the face and throat, severe skin rash, certain disorders related to blood flow to the eyes, irregular heartbeat, angina, and sudden cardiac death.

- distorted, blurred, blurry central vision or sudden decrease in vision (frequency not known).

The side effect dizziness has been reported more frequently in men over 75 years using CIALIS. Diarrhea has been reported more frequently 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 listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can 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 package to protect from moisture.

Store below 25°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 correctly, they are destroyed responsibly and do not enter the environment. Contents of the package and other information right.

6. The active substance in this medicine is

tadalafil

- Each tablet contains 5 mg tadalafil. Each tablet contains 5 mg tadalafil.
- The other ingredients in this medicine are:
 - Tablet core: lactose monohydrate (see 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), talc.

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

CIALIS 5 mg is a light yellow almond-shaped film-coated tablet and is marked on one side with "C 5".

CIALIS 5 mg is available in blister packs of 14, 28, or 84 tablets.

Not all pack sizes may be marketed.

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>.