

PACKAGE LEAFLET: INFORMATION FOR THE USER
Cialis® 20mg film-coated tablets
(tadalafil)

Your medicine is known as the above but will be referred to as CIALIS throughout the remainder of this leaflet.

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 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. CIALIS has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

CIALIS contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation CIALIS works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. The result of this is improved erectile function. CIALIS will not help you if you do not have erectile dysfunction.

It is important to note that CIALIS 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 a medicine for erectile dysfunction.

2. What you need to know before you take CIALIS

Do not take CIALIS if you:

- are allergic to tadalafil or any of the other ingredients of this medicine (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 recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as CIALIS, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Warnings and precautions

Talk to your doctor before taking CIALIS.

Be aware that sexual activity carries a possible risk to patients with heart disease because it puts an extra strain on your heart. If you have a heart problem you should tell your doctor.

Before taking the tablets, 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.

It is not known if CIALIS 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).

If you experience sudden decrease or loss of vision or your vision is distorted, dimmed while you are taking CIALIS, stop taking CIALIS and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking CIALIS and contact your doctor immediately.

CIALIS is not intended for use by women.

Children and adolescents

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

Other medicines and CIALIS

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take CIALIS if you are already taking nitrates.

Some medicines may be affected by CIALIS or they may affect how well CIALIS will work. Tell your doctor or pharmacist if you are already taking:

- 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 (to treat fungal infections) and protease inhibitors for treatment of AIDS or HIV infection
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

CIALIS with drink and alcohol

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well CIALIS will work and should be taken with caution. Talk to your doctor for further information.

Fertility

When dogs were treated there was reduced sperm development in the testes. A reduction in sperm was seen in some men. These effects are unlikely to lead to a lack of fertility.

Driving and using machines

Some men taking CIALIS in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines. CIALIS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

CIALIS contains sodium

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

3. How to take CIALIS

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