

**PATIENT LEAFLET IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

This medicine is dispensed with a physician's prescription only

Cialis 5 mg

Film-coated tablets

The active ingredient and its quantity:

Each tablet contains: tadalafil 5 mg

Inactive ingredients and allergens in the preparation: see Chapter 2 Section "important information about some of the ingredients of this medicine" and Chapter 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any additional questions, contact your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It might harm them even if their illness seems to be the same as yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Cialis 5 mg is indicated for:

The treatment of erectile dysfunction in men.

The treatment of symptoms of benign prostatic hyperplasia (BPH).

The treatment of men with erectile dysfunction and symptoms of benign prostatic hyperplasia (BPH).

Therapeutic group: Urologicals, drugs used in erectile dysfunction.

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

Erectile dysfunction 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.

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.

Benign prostatic hyperplasia is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. Cialis improves blood flow to, and relaxes the muscles of, the prostate and bladder which may

reduce symptoms of benign prostatic hyperplasia. Cialis has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to tadalafil or any of the other ingredients of this medicine (listed in Chapter 6).
- you 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.
- you have serious heart disease or recently had a heart attack within the last 90 days.
- you recently had a stroke within the last 6 months.
- you have low blood pressure or uncontrolled high blood pressure.
- you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as “stroke of the eye”.
- you 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.

This medicine is not intended for use under the age of 18 or by women.

Special warnings regarding the use of this medicine

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.

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with Cialis for benign prostatic hyperplasia. Cialis does not treat prostate cancer.

Before taking the tablets, tell your doctor if you have:

- sickle cell anemia (an abnormality of red blood cells).
- multiple myeloma (cancer of the bone marrow).
- leukemia (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 or 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.

Children and adolescents

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

Drug interactions:

If you are taking or have recently taken other medicines including non-prescription medications and food supplements, inform your doctor or pharmacist.

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.

Taking this medicine with food and drink

Cialis tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken 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.

Taking this medicine and drinking alcohol

Drinking alcohol may affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Cialis, avoid excessive alcohol drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up from a lying down position.

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.

Important information about some of the ingredients of this medicine

Cialis contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult 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 SHOULD YOU USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. You must check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by the doctor.

For the treatment of erectile dysfunction

The acceptable dose is usually one 5 mg tablet taken once a day at approximately the same time of the day. Your doctor may adjust the dose to 2.5 mg based 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 taken once a day Cialis allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Cialis may be useful to men who anticipate having sexual activity two or more times per week.

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.

For the treatment of symptoms of benign prostatic hyperplasia

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

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

Do not take Cialis more than once a day.

Do not exceed the recommended dose.

Crushing/splitting/chewing:

There is no information about crushing/splitting/chewing the tablet. The tablet should be taken in its entirety.

In addition, there is no information regarding the use of the product through a nasogastric tube.

This medicine must be taken at regular intervals, as determined by your attending doctor.

If you have accidentally taken a higher dose

If you have accidentally taken a higher dose you should contact your doctor. You may experience side effects described in section 4.

If you have taken an overdose or if a child has accidentally swallowed this medicine, proceed immediately to a doctor or a hospital's Emergency Room and bring the medicine package with you.

If you forgot to take the medicine

If you forgot to take this medicine at the specified time, take the medicine 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.

Continue treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have additional questions regarding the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, using this medicine may cause side effects in some users. Do not be alarmed by reading the list of side effects; you may not experience any of them. These side effects are normally mild to moderate in nature.

If you experience any of the following side effects stop using the medicine and contact your doctor immediately for medical help:

- allergic reactions including rashes (frequency uncommon).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency uncommon).
- priapism, a prolonged and possibly painful erection after taking Cialis (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision (frequency rare), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

Other side effects have been reported:

Common side effects (seen in 1 to 10 in every 100 patients):

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

Uncommon side effects (seen in 1 to 10 in every 1,000 patients):

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, prolonged erection, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears (tinnitus), swelling of the hands, feet or ankles and feeling tired.

Rare side effects (seen in 1 to 10 in every 10,000 patients):

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

Heart attack and stroke have also been reported rarely in men taking Cialis. Most of these men had known heart problems before taking this medicine.

Partial, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional rare side effects have been reported in men taking Cialis that were not seen in clinical trials. These include:

- migraine, swelling of the face, serious allergic reaction which causes swelling of the face or throat, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

The side effect dizziness has been reported more frequently in men over 75 years of age taking Cialis. Diarrhea has been reported more frequently in men over 65 years of age taking Cialis.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" located on the Home Page of the Ministry of Health's website (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and all other medicines must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the carton and blister. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away this medicine. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Tablet Core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, sodium lauryl sulfate.

Film-coat: Color Mixture Yellow (Y-30-12863-A), talc.

Each tablet contains 121 mg lactose (as monohydrate) (see Chapter 2 Section “Important information about some of the ingredients of this medicine”).

What does this medicine look like and what is the content of the pack

Cialis 5 mg is an almond shaped tablet with light yellow coating. The mark “C 5” is engraved on one side of the tablet.

This medicine comes in blister packs containing 4, 14, 28 or 30 tablets.

Not all pack sizes may be marketed.

Registration holder and address:

Eli Lilly Israel Ltd, 4 HaSheizaf Street, P.O. Box 4246, Ra’anana 4366411

Manufacturer name and address:

Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, USA

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