

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

This medicine is dispensed with a physician's prescription only

Cialis 10 mg

Coated tablets

Composition:

Each tablet contains:
Tadalafil 10 mg to be used "**As Needed**" "

Cialis 20 mg

Coated tablets

Composition:

Each tablet contains:
Tadalafil 20 mg to be used "**As Needed**" "

Cialis 2.5 mg

Coated tablets

Composition:

Each tablet contains:
Tadalafil 2.5 mg for "**Daily**" use

Cialis 5 mg

Coated tablets

Composition:

Each tablet contains:
Tadalafil 5 mg for "**Daily**" use

Read the entire leaflet carefully before using this medicine. This patient leaflet contains concise information about this medicine. If you have any additional questions, please 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. IMPORTANT INFORMATION ABOUT CIALIS:

- **Cialis** may cause a sudden decrease in blood pressure when taken concomitantly with nitrates. Consult your doctor or pharmacist if you are unsure whether the medicines you are taking contain nitrates.
- A patient who has taken **Cialis** and is in need of urgent medical care due to heart problems must inform the medical staff that he is using this drug, to avoid being treated with nitrates!
- **If during sexual activity the following symptoms appear: chest pain, dizziness or nausea, seek immediate medical assistance.** Sexual activity involves a certain risk to heart patients, as it puts an extra strain on the heart.

What is the medication used for?

Cialis is used for the treatment of erectile dysfunction in men, for obtaining and maintaining an erection.

Cialis belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5).

Cialis "Daily" 5 mg is also indicated for:

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

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

When taken for the treatment of erectile dysfunction, Cialis does not work without sexual stimulation.

Cialis exists in several forms, suited to the patient's needs:

Cialis "As Needed"-

Cialis 10 mg and 20 mg enables you to obtain an erection in response to sexual stimulation starting 30 minutes after administration and up to 36 hours afterwards.

The maximal dose is one tablet per day. It is not recommended for permanent daily use.

Cialis "Daily"-

Cialis 2.5 mg and 5 mg.

Taking **Cialis "Daily"** enables you to obtain an erection during sexual stimulation at any point during the 24 hours of the day.

2. BEFORE USING THIS MEDICINE:

Do not use this medicine if:

- You are sensitive to tadalafil or any of the inactive ingredients of this medicine (see section 6 "Additional information").
- You are taking, intermittently or continuously, medicines containing nitrates. Simultaneous use may increase the hypotensive action of these medications.
- You have had myocardial infarction within the last 90 days, you suffer from unstable angina, hypertension or uncontrolled arrhythmias, hypotension (lower than 90/50) or following a stroke that occurred in the past six months.
- You are suffering or have previously suffered from vision loss as a result of a medical condition called NAION.

- You are taking riociguat. This medicine is used to treat high blood pressure in the lungs or 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 in patients under 18 years of age or in women.

Tell your doctor before beginning this treatment if:

- You suffer from sickle cell anemia, multiple myeloma or leukemia.
- You have an anatomical deformation of the penis or other conditions that may cause prolonged erection.
- You are suffering or have previously suffered from impaired cardiac function (sexual activity involves a certain risk to heart patients as it puts an extra strain on the heart).
- You are suffering or have previously suffered from uncontrolled high or low blood pressure.
- You have had a stroke.
- You are suffering or have previously suffered from liver problems.
- You are suffering or have previously suffered from kidney problems.
- You suffer from retinitis pigmentosa, a rare genetic eye disease.
- You are suffering or have previously suffered from impaired vision (see "Side Effects" below).
- You have a gastric ulcer.
- You suffer from bleedings.

Warnings:

- A person who is taking **Cialis** and is in need of medical care, due to chest pain for example, must inform the medical staff that he is taking this medicine, to avoid being treated with nitrates! In case the patient is in need of nitrate treatment, at least 48 hours must pass from the last dose of **Cialis**. Treatment will be conducted only under close medical supervision.
- Using medicines (such as **Cialis**) that belong to the group of phosphodiesterase type 5 inhibitors (PDE5) may cause a rare condition of sudden loss of vision as a result of obstruction of blood flow to the optic nerve (NAION – non-arteritic anterior ischemic optic). Analysis of data suggest that the risk of this condition increases within 1-4 days of taking drugs from this family in patients suffering from erectile dysfunction. This condition may lead to decreased vision and even to blindness.
- Although this condition is rare, inform the doctor if you have suffered in the past from decreased vision or immediately if you feel a change in vision during treatment with the medicine.
- 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.
- **In the event that the erection lasts for over 4 hours, contact your doctor immediately.**

If you are taking other medicines, including non-prescription medications and food supplements, inform your doctor or pharmacist. It is particularly important to inform your doctor or pharmacist if you are taking:

- Nitrate medications (see section "Do not use this medicine if").
- Medicines belonging to the guanylate cyclase stimulators family (such as riociguat) – Do not take concurrently with **Cialis**. Simultaneous use may cause symptomatic hypotension.
- Medicines that belong to the group of alpha blockers (such as doxazosin), used for the treatment of benign prostatic hyperplasia (BPH), or other medications used for the treatment of hypertension – concomitant use may increase the effect (lowering blood pressure) of these medications.
- Medicines that belong to the group of 5 alpha reductase inhibitors (such as finasteride, used for the treatment of benign prostatic hyperplasia (BPH) and hair loss in men) – since no official studies examining the effect of the combination between these two drugs were conducted, you should notify your doctor if you are taking a medication from this group.
- The following medicines may affect the level of **Cialis** in your blood: certain oral antifungal medications (such as ketoconazole and itraconazole); antibiotics from the macrolide family (such as erythromycin and clarithromycin); medicines for the treatment of AIDS virus, that belong to the group of protease inhibitors (such as ritonavir and saquinavir); rifampicin (for the treatment of tuberculosis); phenobarbital (for sleep); phenytoin and carbamazepine (for the treatment of epilepsy); and theophylline (for the treatment of asthma).
- Do not use concomitantly additional medications for the treatment of erectile dysfunction.

Taking Cialis with food and drink:

Cialis may be taken with or without food.

Do not take **Cialis** together with grapefruit juice, as this combination may affect the level of **Cialis** in your blood.

Driving and drinking alcohol:

Before driving or operating machines, make sure that taking this medicine does not involve dizziness.

Drinking alcohol may impair the ability to obtain an erection. It is recommended to avoid excessive alcohol consumption as it may also increase the risk of dizziness when standing up from a lying position.

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.

The acceptable dose, unless otherwise prescribed by your doctor, for the treatment of erectile dysfunction in men, for obtaining and maintaining an erection:

Cialis "As Needed" -

One tablet, at least 30 minutes prior to sexual activity. Do not exceed the recommended dose. Do not take more than one tablet a day. The tablet may be taken at any time during the day. The effect of **Cialis** may last up to 36 hours. Use of this medicine on a daily basis should be avoided, as the effect of **Cialis** lasts more than one day.

Cialis "Daily" -

The recommended dose is one tablet of **Cialis** a day. **Cialis** should be taken every day at approximately the same time.

The acceptable dose, unless otherwise prescribed by your doctor, for the symptomatic treatment of benign prostatic hyperplasia (BPH):

One Cialis 5 mg tablet once a day. **Cialis 5 mg** must be taken every day at approximately the same time.

The acceptable dose, unless otherwise prescribed by your doctor, for the treatment of men suffering from erectile dysfunction and symptoms of benign prostatic hyperplasia (BPH):

One Cialis 5 mg tablet once a day. **Cialis 5 mg** must be taken every day at approximately the same time (regardless of sexual activity timing).

The tablet is coated and therefore must not be split.

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

If you forgot to take this medicine at the specified time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

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 package of this medicine with you. Continue treatment as recommended by your doctor.

4. SIDE EFFECTS:

Like all medicines, using **Cialis** 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.

Stop treatment and contact your doctor immediately if you suffer from:

- A prolonged and painful erection after taking **Cialis**. If the erection lasts continuously for more than 4 hours, you should contact a doctor immediately (rare frequency).
- Sudden loss of vision (rare frequency).
- An allergic reaction (including rash on the skin) (uncommon frequency).
- Chest pain - do not use nitrates and seek immediate medical assistance (uncommon frequency).

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.

Dizziness was reported more frequently in men over 75 years of age who took **Cialis**. Diarrhea was reported more frequently in men over 65 years of age who took **Cialis**.

Uncommon side effects (seen in 1 to 10 in every 1,000 patients): rash, stomach ache, vomiting, nausea, heartburn, blurred vision, eye pain, nose bleeds, difficulty in breathing, prolonged erection, pounding heartbeat sensation, fast heart rate, high blood pressure, low blood pressure, ringing or buzzing in the ear (tinnitus), dizziness, presence of blood in urine, peripheral edema and feeling tired.

Rare side effects (seen in 1 to 10 in every 10,000 patients): Partial, temporary, or permanent decrease or loss of vision in one or both eyes; a sudden decrease or loss of hearing; fainting; epilepsy attack and passing memory loss; swelling of the eyelids; redness of the eyes; hives (itchy red welts on the surface of the skin); blisters or peeling skin; increased sweating; presence of blood in semen; penile bleeding.

Rare cases of cardiac infarction and stroke were reported – in most cases, there was a preexisting heart problem before taking this drug.

Rare side effects that were not seen in clinical trials: migraine, facial edema, 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.

Consult your doctor if one of the side effects becomes worse or if you are suffering from a side effect not mentioned in this leaflet.

Side effects can be reported to the Ministry of Health via an online form in the following link:

<http://forms.gov.il/globgaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.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 of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
- Do not use this medicine after the expiry date (exp. date) which refers to the last day of that month.
- **Cialis 2.5 mg, 10 mg and 20 mg:** Store below 30°C.
- **Cialis 5 mg:** Store below 25°C.
- Store in the original package to protect from moisture.

6. ADDITIONAL INFORMATION:

- In addition to the active ingredient, this medicine also contains:
Tablet Core: Croscarmellose sodium, Hydroxypropyl cellulose, Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose, Sodium lauryl sulfate.
Film-coat: Hypromellose, Titanium dioxide, Triacetin, Iron oxide yellow, Iron oxide red, Talc.

This medicine contains lactose and may cause an allergic reaction in people who are sensitive to lactose:

Each tablet of 2.5 mg contains 87 mg lactose (as monohydrate).

Each tablet of 5 mg contains 121 mg lactose (as monohydrate).

Each tablet of 10 mg contains 170 mg lactose (as monohydrate).

Each tablet of 20 mg contains 233 mg lactose (as monohydrate).

Each tablet contains no more than 2 mg of sodium.

- **What does this medicine look like and what is the content of the package:**

Cialis 2.5 mg is an almond shaped tablet with an orange-yellow coating. The mark "C 2½" is engraved on one side of the tablet. This medicine comes in a carton box of 28 tablets.

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 a carton box of 28 tablets.

Cialis 10 mg is an almond shaped tablet with light yellow coating. The mark "C 10" is engraved on one side of the tablet. This medicine comes in a carton box of 4 tablets.

Cialis 20 mg is an almond shaped tablet with yellow coating. The mark "C 20" is engraved on one side of the tablet. This medicine comes in a carton box of 4 or 8 tablets.

- **License Holder:**
Eli Lilly Israel Ltd, P.O.Box 2160, Herzliya Pituach 4672511
- **Manufacturer:**
Lilly S.A., Alcobendas (Madrid), Spain.
- The content of this leaflet was reviewed and approved by the Ministry of Health on July 2015, and was updated according to the guidelines of the Ministry of Health on November 2017.
- **Drug Registration numbers in the National Drug Registry in the Ministry of Health:**
Cialis 2.5 mg: 139-19-31765-00
Cialis 5 mg: 139-20-31766-00
Cialis 10 mg: 128-19-30677-21
Cialis 20 mg: 128-20-30678-21

I CIALTB A 09