

CIALIS[®] FILM-COATED TABLET

Tadalafil (10, 20mg)

What is in this leaflet

1. What *Cialis* is used for
2. How *Cialis* works
3. Before you use *Cialis*
4. How to use *Cialis*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Cialis*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Cialis* is used for

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

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

How *Cialis* works

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.

Before you use *Cialis***- When you must not use it**

Do not take CIALIS if you:

- are allergic to tadalafil or any of the other ingredients of this medicine .
- 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”.

- Before you start to use it

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.

If you experience sudden decrease or loss of vision, 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.

- Taking other medicines

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 [benign enlargement of the prostate]).
- other medicines to treat high blood pressure.
- 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.
- antacids
- warfarin (anti-coagulant medicine)

How to use *Cialis***- How much to use**

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

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.

The recommended starting dose is 10 or 20 mg taken before sexual activity. Your doctor will decide the suitable dose for you.

When to use it

You may take a CIALIS tablet before sexual activity.

CIALIS may still be effective up to 36 hours after taking the tablet.

- How long to use it

Do not take CIALIS more than once a day. CIALIS 10 mg and 20 mg is intended for use prior to anticipated

sexual activity and is not recommended for continuous daily use.

- If you forget to use it

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.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists, and pharmacists treating you that you are taking Cialis.

- Things you must not do

CIALIS with 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 drinking, since this may increase the risk of dizziness when standing up.

Talk to your doctor for further information.

- Things to be careful of

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 an intolerance to some sugars, contact your doctor before taking this medicine.

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

Side effects

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

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including rashes (frequency very rare).
- chest pain - do not use nitrates but seek immediate medical assistance (frequency very rare).
- prolonged and possibly painful erection after taking CIALIS (frequency very 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).

Other side effects have been reported in clinical trials:

Very Common (≥ 10%)

- headache and dyspepsia (indigestion).

Common (≥ 1% and <10%)

- flushing, back pain, muscle ache, dizziness and nasal congestion.

Uncommon (≥ 0.1% and < 1%)

- conjunctival hyperemia (red eye), sensations described as eye pain and swelling of eyelids

Rare (< 0.1%)

- Changes in colour vision

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 very 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Cialis

- Storage

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from moisture. Do not store above 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

CIALIS 20 mg is a yellow film-coated tablet in the shape of an almond and has "C 20" marked on one side.

CIALIS 10 mg is a light yellow film-coated tablet in the shape of an almond and has "C 10" marked on one side.

- Ingredients

- Active ingredient

The **active** substance is tadalafil. Each tablet contains 10 or 20 mg of tadalafil.

- Inactive ingredients

Tablet core: lactose monohydrate, croscarmellose sodium,

hydroxypropylcellulose,
microcrystalline cellulose, sodium
laurilsulfate, magnesium stearate.

Film-coat: lactose monohydrate,
hypromellose, triacetin, titanium dioxide
(E171), iron oxide yellow (E172), talc.

- *MAL number(s):*

Cialis 10mg Film Coated Tablet
(MAL20034164A)

Cialis 20mg Film Coated Tablet
(MAL20034166A)

Manufacturer

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

Product Registration Holder

Eli Lilly (Malaysia) Sdn Bhd
Level 7, Menara OBYU,
No. 4, Jalan PJU 8/8A,
Damansara Perdana, 47820
Petaling Jaya, Selangor, Malaysia

Date of revision

17 Feb 2015

Serial number

BPFK(R4/1)060215/00027