

CIALIS[®]

Tadalafil 10 mg and 20 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CIALIS. It does not contain all the available information and does not use the place of talking to your doctor or health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CIALIS against the benefits they expect it will have for you.

If you have any concerns about taking CIALIS, ask your doctor or health care professional.

Keep this leaflet with the medicine. You may need to read it again.

What CIALIS is used for

CIALIS is used to treat erectile dysfunction, also known as impotence, in men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

The active ingredient in CIALIS tablets, tadalafil, 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.

Ask your doctor if you have any questions about why CIALIS has been prescribed for you. Your doctor may have prescribed it for another reason.

CIALIS is available only with a doctor's prescription.

Before you take CIALIS

When you must not take it

Do not take CIALIS if:

- **you are currently taking any nitrates or amyl nitrite.** Nitrates are medicines used in the treatment of angina pectoris ("chest pain"). CIALIS has been shown to increase the effects of these drugs. If you are taking any form of nitrate or are unsure tell your doctor.
- **if you have had an allergic reaction in the past to tadalafil or any of the other ingredients of CIALIS listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take CIALIS after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking CIALIS, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

For those who are lactose intolerant, be aware that CIALIS tablets contain a small amount of lactose (approximately 200mg for the 10mg tablet and 250mg for the 20mg tablet).

Tell your doctor if you have or have had any of the following medical conditions:

- you have a heart condition, including angina (chest pain), arrhythmia (changes in the rhythm or rate of the heart beat), heart failure or if you have had a heart attack. Sexual activity carries a possible risk to patients with heart condition because it puts extra strain on your heart
- you have had a stroke
- you have low blood pressure or uncontrolled high blood pressure
- you have a serious liver or kidney problem
- you have sickle cell anaemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), leukaemia (cancer of the blood cells)
- you have any deformation of your penis.

If you have not told your doctor about any of the above, tell them before you start taking CIALIS.

CIALIS is not intended for use by women or by children under the age of 18 years.

No special consideration is needed for the elderly or people with diabetes.

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Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and CIALIS may interfere with each other. This is particularly important if you are treated with:

- nitrates (used to treat heart conditions)
- rifampicin (an antibacterial product used amongst others against tuberculosis),
- ketoconazole or itraconazole (used against fungal infections)
- erythromycin (an antibacterial product)
- protease inhibitors (HIV treatments).

You may need different amounts of your medicines or you may need to use different medicines.

You should not take CIALIS together with any other treatments for erectile dysfunction.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CIALIS.

How to take CIALIS

Carefully follow all directions given to you by your doctor or health care professional. They may differ from the information contained in this leaflet.

How much to take

The recommended dose is 20mg before sexual activity. **You should NOT take CIALIS more than once a day.**

How to take it

CIALIS tablets are for oral use. **Swallow the tablet whole with water.**

You may take CIALIS with or without food or alcohol.

When to take it

You can engage in sexual activity within half an hour of taking the tablet and up to 36 hours later. It may be possible for you to engage in sexual activity more than once – for example, in the evening and again in the morning. The amount of time CIALIS takes to work varies from person to person. After you have taken CIALIS you may wish to attempt sexual intercourse at different times to decide the best time range for you and your partner. Your dose may be lowered to 10mg based on your individual response to CIALIS.

If you are not sure when to take CIALIS, ask your doctor or health care professional.

If you have too much (Overdose)

Immediately telephone your doctor or the National Poisons Centre (0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have had too much CIALIS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include headache, dyspepsia (indigestion), back pain, muscular aches, nasal congestion and facial flushing.

While you are taking CIALIS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CIALIS.

Tell any other doctors, dentists and health care professionals who treat you that you are taking CIALIS.

Things you must not do

Do not use CIALIS to treat any other complaints unless your doctor tells you to.

Do not give CIALIS tablets to others, even if they have similar conditions. Their doctor should decide if CIALIS is right for them.
Things to be careful of

Although the frequency of dizziness in men taking CIALIS was similar to that of men taking placebo (sugar pills) in clinical studies, you should be aware of how you react to CIALIS before you drive or operate machinery.

Side effects

Tell your doctor or health care professional as soon as possible if you do not feel well while you are taking CIALIS. CIALIS helps most people with erectile dysfunction, but it may have unwanted side effects in a few people. Most of the side effects are mild to moderate in nature.

Do not be alarmed by the following list of the most common possible side effects. You may not experience any of them.

Ask your doctor or health care professional to answer any questions you may have.

Tell your doctor or health care professional if you notice any of the following and they are troublesome, severe, or do not go away:

- headache
- indigestion
- back pain
- muscle aches
- nasal congestion
- facial flushing
- swelling of the eyelids
- eye pain
- conjunctival hyperaemia (red eyes)
- dizziness.

Allergic reactions (including skin rashes) could occur.

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In rare instances it is possible that a prolonged and possibly painful erection may occur after taking CIALIS. If you have such an erection which lasts continuously for more than 4 hours, you should contact a doctor immediately.

In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

sodium, hydroxypropylcellulose, microcrystalline cellulose, sodium laurilsulfate, magnesium stearate, hypromellose, triacetin, titanium dioxide (E171), iron oxide (E172) and talc.

Distributor

CIALIS is distributed in New Zealand by:

Eli Lilly and Company (NZ) Ltd.
9 Gladding Place, Manukau City
Auckland
NEW ZEALAND

After taking CIALIS

Storage

Keep your CIALIS tablets in the original package, and store below 25°C. Keep all medicines out of the reach and sight of children.

Disposal

If the expiry date on CIALIS has passed, ask your pharmacist what to do with any medicine that is left over.

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This leaflet was prepared in November 2002.

Product description

What it looks like

CIALIS 10mg tablets are yellow almond-shaped tablets and have "C10" marked on one side. CIALIS 10mg tablets are blister packed and are available in cartons containing 4 tablets. CIALIS 20mg tablets are yellow almond-shaped tablets and have "C20" marked on one side. CIALIS 20mg tablets are blister packed and are available in cartons containing 1, 2 or 4 tablets.

Ingredients

CIALIS tablets contain either 10mg or 20 mg of the active ingredient tadalafil.

CIALIS tablets also contain the following inactive ingredients: lactose monohydrate, croscarmellose