

CIALIS(R)

tadalafil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CIALIS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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 this medicine, talk to your doctor or pharmacist.

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 maintain, 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.

CIALIS will only work if you are sexually aroused.

CIALIS Once-A-Day is for patients who anticipate frequent use of CIALIS (i.e. at least twice weekly).

Your Doctor can advise on the appropriateness of once-a-day treatment.

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.

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

condition because it puts extra strain on the heart

- * **if you have suffered a heart attack or stroke in the last 6 months**
- * **if your blood pressure is unusually high or low or is not effectively treated**
- * **if you have vision loss in one eye because of non-arteritic interior ischaemic optic neuropathy (NAION)**
- * **if you use recreational drugs called "poppers" or "amyl" like amyl nitrite and butyl nitrite that are normally taken through inhalation**

Do not take CIALIS if you have an allergy to:

- * any of the ingredients 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 this medicine after the expiry date printed on the pack.

If it has expired, return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or if the seals over the carton ends are missing or broken. There are no seals over the carton ends of the 5mg physician sample pack.

If it 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.

CIALIS tablets contain a small amount of lactose.

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

- * liver or kidney problems
- * heart problems such as angina, arrhythmias (changes in the rhythm or rate of the heart beat), heart failure, or if you have had a heart attack
- * blood vessel problems
- * 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 the penis (such as angulation, cavernosal fibrosis or Peyronie's disease)
- * loss of vision in one or both eyes

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

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 may be affected by CIALIS or may affect how it works. These include:

- * Nitrates, medicines such as glyceryl trinitrate used to treat angina and other heart conditions
- * Some antibiotic medicines such as rifampicin, erythromycin and clarithromycin
- * Some medicines used to treat seizures such as phenytoin, phenobarbitone and carbamazepine
- * Some medicines used to treat

- fungal infections such as ketoconazole and itraconazole
- * Protease inhibitors used to treat HIV such as ritonavir and saquinavir
- * Medicines used to treat hypertension (high blood pressure)
- * Alpha blockers (used to treat hypertension and some prostate problems)
- * Warfarin, a medicine used to prevent or treat blood clots
- * High doses of alcohol
- * Grapefruit juice
- * PDE5 inhibitors such as sildenafil used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs)

These medicines may be affected by CIALIS or may affect how well it works. You may need different amounts of your medicines or you may need to take 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 this medicine.

How to take CIALIS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

CIALIS can be taken as either on-demand dosing or once-a-day dosing. Do not take once-a-day dosing and on-demand dosing concurrently.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

ON-DEMAND DOSING

You should not take CIALIS more than once a day.

CIALIS 10 and 20 mg is intended for use prior to anticipated sexual activity and is not for continuous daily use.

The maximum recommended dose of CIALIS is one 20 mg tablet taken before sexual activity.

If you have kidney disease, the recommended dose of CIALIS is one 10 mg tablet. This dose may be increased up to 20 mg. For patients with severe renal impairment 10 mg is the maximum recommended dose.

If you have liver disease, the recommended dose of CIALIS is one 10mg tablet. Patients with severe hepatic impairment should follow their doctor's advice.

ONCE-A-DAY DOSING

You should not take CIALIS more than once a day.

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

The recommended dose of CIALIS is one 5 mg tablet taken once per day.

Dosage adjustments are not required in patients with kidney disease.

Once-a-day dosing of CIALIS is not recommended in patients with severe renal impairment.

Patients with liver disease should follow their doctor's advice.

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

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

ON-DEMAND DOSING

CIALIS can be taken with or without

food or alcohol.

CIALIS should be taken prior to anticipated sexual activity.

The amount of time CIALIS takes to work varies from person to person. In some men CIALIS can work as early as 30 minutes after taking the tablet but it is recommended that you allow 1 hour the first time you take it. CIALIS has been proven to be effective for up to 36 hours. This means you can take CIALIS and choose when you want to have sex over the next 36 hours.

For example, you can take CIALIS at Friday lunchtime and you can choose to engage in sexual activity on Friday afternoon, Friday night or anytime on Saturday including Saturday night.

Sometimes if you're feeling anxious or nervous you may not respond to the first tablet. Don't give up, it may take a few doses before you get the full benefit of CIALIS.

CIALIS will only work if you are sexually aroused.

ONCE-A-DAY DOSING

Take CIALIS with water every day at approximately the same time, either with or without food.

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. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Drinking alcohol may affect your ability to get an erection, so avoid excessive drinking with CIALIS.

If you have any questions about taking CIALIS, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or the New Zealand

National Poisons Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken 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 pharmacists who treat you that you are taking CIALIS.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how CIALIS affects you.

Side effects

Tell your doctor or pharmacist 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. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

The following side effects are usually mild and short-lived. In clinical trials, the number of patients taking CIALIS who discontinued due to side effects (1.7%) was not different from the number of patients taking placebo (dummy treatment) (1.1%).

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * facial flushing
- * indigestion
- * back pain
- * chest pain
- * muscle aches
- * diarrhoea
- * heart burn
- * stomach pain
- * allergic reactions, including skin rash, swelling of the face and hives
- * sweating
- * headache or migraine
- * nasal congestion
- * dizziness
- * infection
- * sore throat and discomfort when swallowing
- * red eyes, eye pain and swelling of eyelids are uncommon
- * changes in colour vision are rare
- * decreases or loss of vision are very rare
- * blurred vision
- * bleeding nose
- * prolonged erection
- * fainting

If you experience chest pain during or after sexual activity, stop what

you are doing, sit up and sit forward.

Call an ambulance if the pain does not resolve. Do not use nitrates.

In rare instances it is possible that a prolonged and possibly painful erection may occur after taking CIALIS.

If you have an erection which lasts longer than usual, you should contact a doctor immediately.

When taking CIALIS with large amounts of alcohol, some men may experience dizziness.

Sudden loss or decrease in hearing and seizures have been reported in people taking CIALIS. It is not possible to determine whether these events are related directly to CIALIS, to other diseases or medications, to other factors, or to a combination of factors. If you experience these symptoms, stop taking CIALIS and contact a doctor immediately.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

Potential withdrawal effects from daily use have not been examined. It is recommended that patients continue to be monitored by their doctor after discontinuation of CIALIS.

If you notice any symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything on this list.

After taking CIALIS

Storage

Keep your tablets in the original pack until it is time to take them.

If you take the tablets out of the pack they may not keep as well.

Keep your tablets in a cool dry place where the temperature stays

below 25 degrees C.

Do not store CIALIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CIALIS 5 mg tablets are yellow, film coated, almond shaped tablets, marked "C5" on one side.

CIALIS 10 mg tablets are light yellow, film coated, almond shaped tablets, marked "C10" on one side.

CIALIS 20 mg tablets are yellow, film coated, almond shaped tablets, marked "C20" on one side.

Ingredients

Active Ingredients

- * 5 mg tablet - tadalafil 5 mg
- * 10 mg tablet - tadalafil 10 mg
- * 20 mg tablet - tadalafil 20 mg

Other Ingredients

- * croscarmellose sodium
- * hydroxypropylcellulose
- * hypromellose
- * iron oxide yellow CI77492
- * lactose
- * magnesium stearate
- * cellulose - microcrystalline

- * sodium lauryl sulfate
- * talc - purified
- * titanium dioxide
- * glycerol triacetate (triacetin)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

CIALIS is a product of:

Eli Lilly Australia Pty Limited
112 Wharf Road
West Ryde, NSW 2114
AUSTRALIA

CIALIS is distributed in New Zealand by:

Eli Lilly and Company (NZ) Limited
Level 3, Axon House
414-422 Khyber Pass Road,
Newmarket
PO Box 109 197, Newmarket
Auckland
NEW ZEALAND
(R) = Registered Trademark

Australian Registration Number

CIALIS 5 mg tablet - AUST R
128496
CIALIS 10 mg tablet - AUST R
90590
CIALIS 20 mg tablet - AUST R
81137

Further Information

For further information on this product please visit the following websites

Australian residents:
www.cialis.com.au

This leaflet was revised in September 2009