



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What CIALIS is and what it is used for
2. Before you take CIALIS
3. How to take CIALIS
4. Possible side effects
5. Storing CIALIS
6. Further information

CIALIS 10 mg film-coated tablets

tadalafil

The active substance is tadalafil. Each tablet of CIALIS contains 10 mg of tadalafil.

The other ingredients are:

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.

Marketing Authorisation Holder: Lilly ICOS Limited, 25 New Street Square, London, EC4A 3LN. United Kingdom.

Manufacturer: Eli Lilly and Company Ltd., Kingsclere Road, Basingstoke, Hampshire, RG21 6XA. United Kingdom.

1. WHAT CIALIS IS AND WHAT IT IS USED FOR

CIALIS comes as light yellow film-coated tablets. They are in the shape of almonds and have "C 10" marked on one side. These tablets are available in blister packs containing 4 tablets.

CIALIS is a treatment for men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

CIALIS 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.

2. BEFORE YOU TAKE CIALIS

Do not take CIALIS:

- if 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 drugs. If you are taking any form of nitrate or are unsure tell your doctor.
- if you have serious heart disease or have had a recent heart attack.
- if you have had a recent stroke.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you are (hypersensitive) allergic to tadalafil or any of the other ingredients of CIALIS.

Take special care with CIALIS:

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.

The following are reasons why CIALIS may also not be suitable for you. If any of them apply to you, talk to your doctor before you take the medicine:

- You have sickle cell anaemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), leukaemia (cancer of the blood cells) or any deformation of your penis.
- You have a serious liver or kidney problem.

Taking other medicines:

As a general rule, always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed, because occasionally they might interact. This is particularly important if you are treated with nitrates as you should not take CIALIS if you are taking these medicines. Do not take CIALIS with other medicines if your doctor tells you that you may not.

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

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

Driving and using machines:

As dizziness has been reported in men taking CIALIS in clinical studies, you should be aware of how you react to CIALIS before you drive or operate machinery.

Information for men intolerant of lactose, one of the ingredients of CIALIS:

CIALIS contains lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

3. HOW TO TAKE CIALIS

Always take CIALIS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended starting dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak your doctor may increase the dose to 20 mg. CIALIS tablets are for oral use. Swallow the tablet whole with some water. You may take CIALIS with or without food.

You may take a CIALIS tablet at any point in time from 30 minutes to 12 hours before sexual activity. CIALIS may still be effective up to 24 hours after taking the tablet. 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.

You should NOT take CIALIS more than once a day. Daily use of CIALIS is strongly discouraged.

If you take more CIALIS than you should:

Tell your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, CIALIS can have side effects. These effects are normally mild to moderate in nature.

The most common undesirable effects are headache and indigestion. Less commonly reported side effects are back pain, muscle aches, nasal congestion, facial flushing and dizziness. Uncommon effects are swelling of the eyelids, eye pain and red eyes.

If you have any of these side effects and they are troublesome, severe, or do not go away, tell your doctor.

Allergic reactions (including skin rashes) could occur.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Heart attack, stroke, and irregular heart beats have been reported rarely in men taking CIALIS. Most, but not all of these men had known heart problems before taking this medicine. It is not possible to determine whether these events were directly related to CIALIS.

Effects were seen in one animal species that might indicate impairment of fertility. Subsequent studies in man suggest that this effect is unlikely in humans.

5. STORING CIALIS

Keep out of the reach and sight of children.

Store in the original package.

Do not use after the expiry date stated on the carton and blister.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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