

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### CIALIS 5 mg film-coated tablets tadalafil

#### **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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What CIALIS is and what it is used for
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### **1. WHAT CIALIS IS AND WHAT IT IS USED FOR**

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 allergic (hypersensitive) to tadalafil or any of the other ingredients of 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 medicines. 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 have ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition sometimes described as “stroke of the eye”.

### **Take special care with 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.

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 problem.
- You have a severe kidney problem.

It is not known if CIALIS is effective in patients who have undergone pelvic surgery or radical non-nerve-sparing prostatectomy

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 or by adolescents under the age of 18.

### **Using other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because 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.

A type of medicine called an alpha blocker is sometimes used to treat high blood pressure and enlarged prostate. Tell your doctor if you are being treated for either of these conditions or if you take other medicines to treat high blood pressure.

If you are taking medicines that can inhibit an enzyme called CYP3A4 (for example ketoconazole or protease inhibitors for treatment of HIV) the frequency of side effects might increase.

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.

### **Taking CIALIS with food and drink**

You may take CIALIS with or without food.

Information on the effect of alcohol is in section 3.

### **Driving and using machines**

Some men taking CIALIS in clinical studies have reported dizziness. Check carefully how you react to the medicines before driving or using any machinery.

### **Important information about some of the ingredients of CIALIS:**

CIALIS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. HOW TO TAKE CIALIS**

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

Once a day dosing of CIALIS may be useful to men who anticipate having sexual activity two or more times per week. The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day. Your doctor may adjust the dose to 2.5 mg based on your response to CIALIS. CIALIS tablets are for oral use. Swallow the tablet whole with some water. You may take CIALIS 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. 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.

Drinking alcohol may affect your ability to get an erection. Drinking alcohol may temporarily lower your blood pressure. If you have taken or are planning to take CIALIS, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

You should NOT take CIALIS more than once a day.

#### **If you take more CIALIS than you should**

Tell your doctor.

#### **If you forget to take CIALIS**

Do not take a double dose to make up for a forgotten tablet.

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

### **4. POSSIBLE SIDE EFFECTS**

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

In this leaflet, when a side effect is described as “very common” this means that it has been reported in at least 1 in 10 patients taking the medicine. When a side effect is described as “common” this means that it has been reported in more than 1 in every 100 patients but less than 1 in every 10 patients. When a side effect is described as “uncommon”, this means it has been reported in more than 1 in every 1,000 patients, but less than 1 in every 100 patients. When a side effect is described as “rare”, this means it has been reported in more than 1 in every 10,000 patients, but less than 1 in every 1,000 patients.

Very commonly reported side effects in patients taking CIALIS were headache.

Commonly reported side effects in patients taking CIALIS include back pain, muscle aches, facial flushing, nasal congestion, dizziness and indigestion.

Uncommon side effects are allergic reactions including rashes, abdominal pain, reflux, blurred vision, eye pain, increased sweating, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure and chest pain. In case of chest pain occurring during or after sexual activity you should NOT use nitrates but you should seek immediate medical assistance.

Rare side effects in patients taking CIALIS include fainting, migraine, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives and nose bleeds.

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.

Heart attack and stroke have also 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.

Partial, sudden, temporary, or permanent decrease or loss of vision in one or both eyes has been rarely reported.

Some additional side effects have been reported in men taking CIALIS at an estimated frequency of rare that were not seen in clinical trials. These include migraine, swelling of the face, serious skin rashes, some disorders affecting blood flow to the eyes, irregular heartbeats, angina and sudden cardiac death.

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, although a decrease in sperm concentration was seen in some men.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE CIALIS**

Keep out of the reach and sight of children.

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

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

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.

## **6. FURTHER INFORMATION**

### **What CIALIS contains**

The active substance is tadalafil. Each tablet contains 5 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.

### **What CIALIS looks like and contents of the pack**

CIALIS 5 mg strength comes as light yellow film-coated tablets. They are in the shape of almonds and have "C 5" marked on one side.

CIALIS 5 mg is available in blister packs containing 14 or 28 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

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**This leaflet was last approved in {date}**

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu>