

## Package leaflet: Information for the user

### <Product name> 5 mg

film-coated tablets

Tadalafil

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

#### 1. What <Product name> is and what it is used for

<Product name> 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. The active substance of <Product name>, tadalafil, has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

<Product name> belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation <Product name> 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. <Product name> will not help you if you do not have erectile dysfunction.

It is important to note that <Product name> 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. What you need to know before you take <Product name>

##### Do not take <Product name> if you

- are allergic to tadalafil or any of the other ingredients of this medicine (listed in section 6);
- 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”). Tadalafil 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”;
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as <Product name>, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

### **Warnings and precautions**

Talk to your doctor before taking <Product name>.

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.

It is not known if tadalafil is effective in patients who have had:

- pelvic surgery;
- removal of all or part of the prostate gland in which nerves of the prostate are cut (radical non-nerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision, stop taking <Product name> and contact your doctor immediately.

<Product name> is not intended for use by women.

### **Children and adolescents**

<Product name> is not intended for use by children and adolescents under the age of 18.

### **Other medicines and <Product name>**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take <Product name> if you are already taking nitrates.

Some medicines may be affected by <Product name> or they may affect how well <Product name> 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);
- other medicines to treat high blood pressure;
- riociguat;
- a 5-alpha reductase inhibitor (used to treat benign prostatic hyperplasia);
- 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.

### **<Product name> with drink and alcohol**

Information on the effect of alcohol is in section 3.

Grapefruit juice may affect how well <Product name> will work and should be taken with caution. Talk to your doctor for further information.

### **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.

### **Driving and using machines**

Some men taking tadalafil in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

### **<Product name> 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 <Product name>**

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

<Product name> tablets are for oral use in men only. Swallow the tablet whole with some water. You may take <Product name> with or without food.

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 <Product name> (2.5 mg tablets are available on the market).

Do not take <Product name> more than once a day.

Once a day dosing of <Product name> may be useful to men who anticipate having sexual activity two or more times per week.

When taken once a day <Product name> 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 <Product name> 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 and may temporarily lower your blood pressure. If you have taken or are planning to take <Product name>, avoid excessive drinking (blood alcohol level of 0.08% or greater), since this may increase the risk of dizziness when standing up.

### **If you take more <Product name> than you should**

Contact your doctor. You may experience side effects described in section 4.

### **If you forget to take <Product name>**

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 <Product name> more than once a day.

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

## **4. Possible 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 uncommon);
- chest pain – do not use nitrates but seek immediate medical assistance (frequency uncommon);
- prolonged and possibly painful erection after taking <Product name> (frequency 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:

**Common** (may affect up to 1 in 10 people)

- headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

**Uncommon** (may affect up to 1 in 100 people)

- dizziness, stomach ache, feeling sick, being sick (vomiting), reflux, blurred vision, eye pain, difficulty in breathing, presence of blood in urine, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds, ringing in the ears, swelling of the hands, feet or ankles and feeling tired.

**Rare** (may affect up to 1 in 1,000 people)

- fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing, hives (itchy red welts on the surface of the skin), penile bleeding, presence of blood in semen and increased sweating.

Heart attack and stroke have also been reported rarely in men taking tadalafil. 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 side effects** have been reported in men taking tadalafil 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.

The side effects dizziness has been reported more frequently in men over 75 years of age taking tadalafil. Diarrhoea has been reported more frequently in men over 65 years of age taking tadalafil.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store <Product name>**

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

This medicinal product does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

**What <Product name> contains**

- The active substance is tadalafil.  
<Product name> 5 mg: each tablet contains 5 mg of tadalafil.
- The other ingredients are:  
Tablet core: lactose monohydrate, microcrystalline cellulose, povidone 25, croscarmellose sodium, magnesium stearate, sodium laurilsulfate.  
Tablet coating: opadry yellow (hypromellose 6cp, titanium dioxide (E171), macrogol 400, ferric oxide yellow (E172), ferric oxide red (E172)).

**What <Product name> looks like and contents of the pack**

<Product name> 5 mg is yellow round biconvex film-coated tablets, diameter 6 mm.  
<Product name> 5 mg is available in blister packs (PVC/PVdC / Al or OPA/AL/PVC / Al) containing 2, 4, 8, 10, 12, 20, 30, 50 and 100 film-coated tablets.  
Not all pack sizes may be marketed.

**Marketing authorisation holder and manufacturer**

[To be completed nationally]

**This medicinal product is authorised in the member states of the EEA under the following names**

[To be completed nationally]

**This leaflet was last revised in** [To be completed nationally].