

## Package leaflet: Information for the user

### Tadalafil 2.5 mg film-coated tablets

### Tadalafil 5 mg film-coated tablets

### Tadalafil 10 mg film-coated tablets

### Tadalafil 20 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 Tadalafil tablets is and what it is used for
2. What you need to know before you take Tadalafil tablets
3. How to take Tadalafil tablets
4. Possible side effects
5. How to store Tadalafil tablets
6. Contents of the pack and other information

#### **1. What Tadalafil tablets is and what it is used for**

Tadalafil 2.5 mg, 5 mg, 10 mg and 20 mg

Tadalafil tablets contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. Following sexual stimulation tadalafil 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. Tadalafil will not help you if you do not have erectile dysfunction.

It is important to note that tadalafil 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.

Tadalafil 2.5 mg, 5 mg, 10 mg and 20 mg tablets are treatment for adult men with erectile dysfunction. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity. Tadalafil has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity.

Tadalafil 5 mg only

Tadalafil 5 mg tablet is used to treat adult men with urinary symptoms associated with a common condition called **benign prostatic hyperplasia**. This is when the prostate gland gets bigger with age. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. Tadalafil improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Tadalafil has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment.

#### **2. What you need to know before you take Tadalafil tablets**

**Do not take Tadalafil tablets 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 tadalafil, 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 or pharmacist before taking Tadalafil tablets.

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.

**Tadalafil 5 mg only**

Since benign prostatic hyperplasia and prostate cancer may have the same symptoms, your doctor will check you for prostate cancer before starting treatment with tadalafil for benign prostatic hyperplasia. Tadalafil tablets does not treat prostate cancer.

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 nonnerve-sparing prostatectomy).

If you experience sudden decrease or loss of vision or your vision is distorted, dimmed while you are taking tadalafil, stop taking Tadalafil tablets and contact your doctor immediately.

Decreased or sudden hearing loss has been noted in some patients taking tadalafil. Although it is not known if the event is directly related to tadalafil, if you experience decreased or sudden hearing loss, stop taking Tadalafil tablets and contact your doctor immediately.

Tadalafil is not intended for use by women.

**Children and adolescents**

Tadalafil is not intended for use by children and adolescents under the age of 18.

**Other medicines and Tadalafil tablets**

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

Do not take Tadalafil tablets if you are already taking nitrates.

Some medicines may be affected by tadalafil or they may affect how well tadalafil 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.

#### **Tadalafil tablets with drink and alcohol**

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well tadalafil 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.

#### **Tadalafil tablets contains lactose and sodium**

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

### **3. How to take Tadalafil tablets**

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

#### **For the treatment of erectile dysfunction**

Tadalafil 10 mg and 20 mg only

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.

You may take a Tadalafil tablets at least 30 minutes before sexual activity. This medicine may still be effective up to 36 hours after taking the tablet.

Do not take this medicine more than once a day. Tadalafil 10 mg and 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

Tadalafil 2.5 mg and 5 mg only

If you anticipate a frequent use of tadalafil (i.e., at least twice weekly) a once daily dose with the lowest doses of tadalafil might be suitable for you, based on your choice and your doctor's judgement. 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 tadalafil. This will be given as a 2.5 mg tablet.  
Do not take Tadalafil tablets more than once a day.

Once a day dosing of Tadalafil tablets may be useful to men who anticipate having sexual activity two or more times per week.

When taken once a day Tadalafil tablets allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day.

Tadalafil 2.5 mg, 5 mg, 10 mg and 20 mg

It is important to note that tadalafil 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 Tadalafil tablets, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

Tadalafil 5mg only

**For the treatment benign prostatic hyperplasia**

The dose is one 5 mg tablet taken once a day at approximately the same time of the day. If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day.

Do not take Tadalafil tablets more than once a day.

Tadalafil 2.5 mg, 5 mg, 10 mg and 20 mg

**Method of administration**

Tadalafil tablets are for oral use in men only. Swallow the tablet whole with some water. The tablets can be taken with or without food.

**If you take more Tadalafil tablets than you should**

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

**If you forget to take Tadalafil tablets**

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 Tadalafil tablets 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:**

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

- allergic reactions including rashes.
- chest pain - do not use nitrates but seek immediate medical assistance.

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

- Priapism, a prolonged and possibly painful erection after taking tadalafil. If you have such an erection, which lasts continuously for more than 4 hours you should contact a doctor immediately.
- sudden loss of vision.

**Not Known**

- distorted, dimmed, blurred central vision or sudden decrease of vision

**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
- 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
- prolonged erection
- 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
- 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
- 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 rare 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
- sudden cardiac death.

#### **Not Known**

- distorted, dimmed, blurred central vision or sudden decrease of vision

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, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Tadalafil tablets**

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

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

This medicinal product does not require any special storage conditions.

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 Tadalafil tablets contain**

- The active substance is tadalafil.
  - Each 2.5 mg film-coated tablet contains 2.5 mg of tadalafil
  - Each 5 mg film-coated tablet contains 5 mg of tadalafil
  - Each 10 mg film-coated tablet contains 10 mg of tadalafil
  - Each 20 mg film-coated tablet contains 20 mg of tadalafil
- The other ingredients are
  - Tablet core: Lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, sodium laurylsulphate, microcrystalline cellulose, magnesium stearate.
  - 2.5 mg and 5 mg film-coat: Opadry Yellow 03K520010 contains HPMC 2910/ Hypromellose, titanium dioxide (E171), triacetin, talc, iron oxide yellow (E172), iron oxide red (E172).
  - 10 mg and 20 mg film coat: Opadry II Yellow 32K12884 contains lactose monohydrate, HPMC 2910/ Hypromellose, titanium dioxide (E171), triacetin, iron oxide yellow (E172).

#### **What Tadalafil tablets looks like and contents of the pack**

Tadalafil tablets are available in four strengths:

Tadalafil 2.5 mg film-coated tablets

Pale pinkish yellow, circular, biconvex film-coated tablet with “T 2.5” debossed on one side and plain on other side.

Diameter:  $6.10 \pm 0.20$  mm.

Tadalafil 5 mg film-coated tablets

Pale pinkish yellow, circular, biconvex film-coated tablet with “T5” debossed on one side and plain on other side.

Diameter:  $8.10 \pm 0.20$  mm.

Tadalafil 10 mg film-coated tablets

Yellow coloured, capsule shaped, biconvex film-coated tablet with “T10” debossed on one side and plain on other side.

Length:  $10.30 \pm 0.20$  mm.

Breadth:  $5.30 \pm 0.20$  mm.

Tadalafil 20 mg film-coated tablets

Yellow coloured, capsule shaped, biconvex film-coated tablet with “T20” debossed on one side and plain on other side.

Length:  $14.10 \pm 0.20$  mm.

Breadth:  $6.10 \pm 0.20$  mm.

Tadalafil tablets are supplied as:

Tadalafil 2.5 mg film-coated tablets

Aluminium/PVC/PE/ PVDC blisters in cartons of 28 film-coated tablets.

Tadalafil 5 mg film-coated tablets

Aluminium/PVC/PE/ PVDC blisters in cartons of 14, 28 or 84 film-coated tablets.

Tadalafil 10 mg film-coated tablets

Aluminium/PVC/PE/ PVDC blisters in cartons of 4 film-coated tablets.

Tadalafil 20 mg film-coated tablets

Aluminium/PVC/PE/ PVDC blisters in cartons of 2, 4, 8, 10, or 12 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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