

## Package leaflet: Information for the user

### Tadalafil Clonmel 10 mg film-coated tablets tadalafil

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- 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.
- If you have taken Tadalafil Clonmel as directed (see section 3) and were not able to get or keep an erection hard enough for satisfactory sex, you should talk to your pharmacist or doctor.

#### **What is in this leaflet**

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

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

Tadalafil Clonmel 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. Tadalafil Clonmel has been shown to significantly improve the attainment of a hard, erect penis suitable for sexual activity.

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

It is important to note that Tadalafil Clonmel 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 Tadalafil Clonmel**

##### **DO NOT take Tadalafil Clonmel if you**

- do not have an **erection problem**, as this medicine will not provide any benefit to you.
- are allergic to **tadalafil** or any of the other ingredients of this medicine (listed in section 6).
- take any medicines called **nitrates** or nitric oxide donors for chest pain (angina pectoris) or heart failure (see "Other medicines and Tadalafil Clonmel").
- take **amyl nitrite**, ("poppers") recreationally.
- have been advised by your doctor to avoid sexual activity because of a **problem with your heart or blood vessels**.
- get **chest pain** during sexual intercourse.

- have a **severe heart or blood vessel problem** such as recent heart attack (within the last 90 days) or stroke (within the last 6 months), unstable angina (chest pain caused by reduced blood flow to the heart muscle) or severe heart failure.
- have **low blood pressure or uncontrolled high blood pressure**.
- have ever had loss of vision because of **non-arteritic anterior ischaemic optic neuropathy** (NAION), a condition described as a stroke in the eye.
- take **riociguat** (or other medicines belonging to a group called guanylate cyclase stimulators) for high blood pressure in the lungs (see "Other medicines and Tadalafil Clonmel").
- are a **woman**.
- are **under 18** years of age.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Tadalafil Clonmel.

Sexual activity can put extra strain on your heart. If you have a heart problem or think you might have a heart problem you should tell your doctor or pharmacist.

Even if you feel healthy, your erection problems may be linked to a serious health condition. Erectile dysfunction may be an early sign of:

- heart and blood vessel problems
- diabetes
- high blood pressure
- depression

You should discuss your symptoms and these conditions with your doctor if you have not already done so. Make an appointment with your doctor at the earliest opportunity to discuss your health before using Tadalafil Clonmel.

Before taking Tadalafil Clonmel, in order to ensure this medicine is suitable for you and that you are fit enough to have sex, talk to your doctor if you:

- get **very breathless or feel any pain in the chest with light or moderate activity** (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have or have ever had **any heart disease or heart surgery**, e.g. damaged or diseased heart valve (valvular heart disease), disease of the heart muscle (cardiomyopathy), irregular heart-beat (arrhythmia).

Before taking Tadalafil Clonmel, talk to your doctor if you:

- have ever had **an erection that lasted more than 4 hours** (called priapism) or have any condition which can cause priapism, including sickle cell anaemia (an abnormality of red blood cells), leukaemia (blood cell cancer), or multiple myeloma (bone marrow cancer). Use of medicines for erectile dysfunction may increase the risk of priapism. Long lasting erection may cause damage to the tissue of the penis and permanent loss of ability to have an erection.
- take any other medicines listed in this leaflet. Please refer to section 2 "Other medicines and Tadalafil Clonmel".
- have any **deformation of your penis**.
- have a **serious liver problem**.
- have a **severe kidney problem**.

It is not known if Tadalafil Clonmel 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).

Talk to your doctor if any of the above applies to you.

#### Vision and hearing

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

#### **Children and adolescents**

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

#### **Other medicines and Tadalafil Clonmel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Tadalafil Clonmel or Tadalafil Clonmel vice-versa, and this may result in side effects.

Before taking other medicines you should also tell your doctor or pharmacist if you have taken Tadalafil Clonmel within the last 48 hours, as Tadalafil Clonmel may still be in your body.

#### **Do not take Tadalafil Clonmel with:**

**NITRATE medicines** Tadalafil Clonmel such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate or nitric oxide donors such as amyl nitrite ("poppers"), nicorandil, molsidomine or sodium nitroprusside.

These are often used for the relief of chest pain (angina pectoris), or heart failure. Taking Tadalafil Clonmel with any of these medicines may lead to a dangerous fall in blood pressure.

**Riociguat** Tadalafil Clonmel or other medicines known as guanylate cyclase stimulators. Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Tadalafil Clonmel.

Talk to your doctor or pharmacist before taking Tadalafil Clonmel if you are already taking:

- an alpha blocker such as **alfuzosin**, **doxazosin** or **tamsulosin**, which are medicines used to treat urinary problems due to an enlarged prostate (benign prostatic hyperplasia) or occasionally high blood pressure, as Tadalafil Clonmel may not be suitable for you. It may lead to dizziness, light-headedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
- other medicines to treat high blood pressure, as Tadalafil Clonmel may lead to low blood pressure.
- medicines to treat fungal infections called **itraconazole** or **ketoconazole** as they increase the concentration of tadalafil and may result in side effects.
- protease inhibitors (**ritonavir**, **saquinavir**) for treatment of AIDS or HIV infection, as they increase the concentration of tadalafil and may result in side effects.
- an antibiotic called **rifampicin**, as it decreases the concentration of tadalafil and may reduce its efficacy Tadalafil Clonmel.
- antibiotics called **erythromycin** or **clarithromycin**, as they increase the concentration of tadalafil and may result in side effects.
- **phenobarbital**, **phenytoin** and **carbamazepine** (anticonvulsant medicines), as they reduce the concentration of tadalafil and may reduce its efficacy Tadalafil Clonmel.
- other treatments for erectile dysfunction. The safety and efficacy of combining tadalafil with other treatments for erectile dysfunction has not been studied and this combination is therefore not recommended.
- **theophylline** (to treat asthma).

- a 5- alpha reductase inhibitor (**finasteride**) to treat benign prostatic hyperplasia.

#### **Tadalafil Clonmel with drink and alcohol**

- Grapefruit juice may affect how Tadalafil Clonmel works and should be taken with caution.
- Drinking large amounts of alcohol may temporarily affect your ability to get an erection and may temporarily lower your blood pressure and make you feel dizzy. To get the maximum benefit from your medicine avoid excessive alcohol intake.

Talk to your doctor or pharmacist for further information.

#### **Pregnancy, breast-feeding and fertility**

This medicine should not be used by women.

In canine testing, reduced sperm development in the testes was observed. 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. Carefully observe how you react to the tablets before driving or using machines.

#### **Tadalafil Clonmel 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 medicine.

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

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

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

#### **Dose**

- Take one tablet, when needed, approximately 30 minutes before you expect to have sexual activity.
- Do not take more than one tablet a day. You can get an erection, when sexually stimulated, in 30 minutes and for up to 36 hours after taking.

#### **Method of administration**

Swallow tablet whole with some water. The tablets can be taken with or without food.

#### Additional information

You will not get an erection just by taking Tadalafil Clonmel. This medicine will only help you get an erection if you are sexually aroused. You and your partner will need to engage in foreplay, just as you would if you were not taking a medicine for erectile dysfunction.

Remember to relax and be patient. There is no rush. If you are not successful the first time, try to have sex again, but remember **do not take more than one tablet a day**. For most men, Tadalafil Clonmel will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you are able to achieve an erection. If you feel the effect of Tadalafil Clonmel is too strong or too weak, talk to your pharmacist or doctor.

Talk to your doctor or pharmacist if you have taken Tadalafil Clonmel as directed and are still not able to get and keep an erection.

#### **Duration of treatment**

Tadalafil Clonmel is not recommended for continuous daily use. Talk to your doctor if you feel you need to take this medicine frequently (i.e. at least twice weekly).

#### **If you take more Tadalafil Clonmel than you should**

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

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 or moderate in nature.

#### **If you experience any of the following side effects stop taking the medicine and seek medical help immediately**

- an allergic reaction: this is uncommon. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat, rashes.
- chest pain: this is uncommon. If this occurs before, during or after intercourse get in a semi-sitting position and try to relax. Do not use nitrates but seek immediate medical assistance.
- priapism, a prolonged and possibly painful erection after taking Tadalafil Clonmel: this is rare. If you have an erection which lasts continuously for more than 4 hours you should contact a doctor immediately.
- a sudden decrease or loss of vision: this occurs rarely, distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

#### **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)
- acid reflux
- blurred vision
- eye pain
- difficulty breathing
- presence of blood in urine
- prolonged erection
- sensation of a pounding heartbeat
- a fast heart rate

- high blood pressure
- low blood pressure
- nosebleed
- 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
- temporary 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 heartbeat
- angina
- sudden cardiac death
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known)

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 HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

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

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 medicine 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 Clonmel contains

- The **active** substance is tadalafil.  
Each film-coated tablet contains 10 mg tadalafil.

- The other ingredients are:

#### Tablet core

Lactose monohydrate  
Croscarmellose sodium  
Sodium laurilsulfate (E487)  
Hydroxypropyl cellulose  
Polysorbate 80  
Cellulose, microcrystalline  
Magnesium stearate

#### Coating

Hypromellose 2910  
Lactose monohydrate  
Titanium dioxide (E171)  
Triacetin  
Iron oxide yellow (E172)  
Talc

### What Tadalafil Clonmel looks like and contents of the pack

Yellow, round, biconvex, film-coated tablets with score line on one side, white at the cross section with  $8.1 \pm 0.2$  mm diameter. The tablets can be divided into equal doses.

Available in blister packs containing 2x1,4x1, 8x1 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### Manufacturer

STADA Arzneimittel AG, Stadastraße 2-18, D-61118 Bad Vilbel, Germany  
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland  
STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

### This medicinal product is authorised in the Member States of the EEA under the following names:

|                  |                                             |
|------------------|---------------------------------------------|
| The Netherlands: | Tadalafil STADA 10 mg filmomhulde tabletten |
| Ireland:         | Tadalafil Clonmel 10 mg film-coated tablet  |
| Norway:          | Tadalafil STADA                             |

**This leaflet was last revised in August 2025.**