

Package leaflet: Information for the user

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

Tadalafil Clonmel contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Tadalafil Clonmel is used to treat 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 your ability to obtain this.

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

- 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 had a heart attack within the last 90 days
- 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 ischaemic optic neuropathy (NAION), also known as “eye stroke”
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs caused by 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 before taking Tadalafil Clonmel.

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 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)

If you experience sudden decrease or loss of vision, 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 this, stop taking Tadalafil Clonmel and contact your doctor immediately.

Tadalafil Clonmel is not intended for use by women.

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

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

Some medicines may be affected by Tadalafil Clonmel or they may affect how well Tadalafil Clonmel 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 Clonmel with drink and alcohol

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Tadalafil Clonmel will work and should be consumed with caution. Talk to your doctor for further information.

Fertility

In animal testing there was reduced sperm development in the testes. A reduction in sperm count 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. See how you react to the tablets before driving or using machines.

Tadalafil Clonmel contains lactose

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

Tadalafil Clonmel contains sodium

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

3. How to take Tadalafil Clonmel

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

Dosage

The recommended starting dose is 10 mg of tadalafil before sexual activity.

However, you have been given the dose of one 20 mg tablet as your doctor has decided that the recommended dose of 10 mg is too weak.

Not all dosing recommendations are possible using the 20 mg tablets; tadalafil may also be available as 2.5, 5 and 10 mg tablets. Not all dosage strengths may be marketed.

Method of administration

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

The tablet can be divided into equal doses: push the tablet downward with one finger on a solid surface in order to break the tablet.

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

Do not take Tadalafil Clonmel more than once a day. Doses of 10 mg and 20 mg are intended for use prior to anticipated sexual activity and are not recommended for continuous daily use.

Please note

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.

Drinking alcohol may also affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or are planning to take Tadalafil Clonmel, avoid excessive drinking (e.g. more than 900 ml beer or 350 ml wine), since this may increase the risk of dizziness when standing up.

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 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)
- priapism, a prolonged and possibly painful erection after taking Tadalafil Clonmel (frequency rare).
If you have 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
- 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
- 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
- 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 heartbeats
- angina
- sudden cardiac death

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 medicinal product does not require any special storage conditions.

Divided tablets should be disregarded after 4 weeks of storage.

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.
One film-coated tablet contains 20 mg tadalafil.
- The other ingredients are:
Tablet core
Lactose monohydrate
Croscarmellose sodium
Sodium laurilsulfate (E487)
Hydroxypropyl cellulose
Polysorbate

Cellulose, microcrystalline
Magnesium stearate

Coating

Hypromellose
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 cross line on both sides, white at the cross section with 10.1 ± 0.2 mm diameter. The tablets can be divided into equal doses.

Available in blister packs containing 4x1, 8x1, 12x1, 16x1, 20x1, 24x1, 28x1, 30x1, 36x1, 48x1, 56x1 and 60x1 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
STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

The Netherlands:	Tadalafil STADA 2,5 mg, 5 mg, 10 mg, 20 mg filmomhulde tabletten
Austria:	Tadalafil STADA 5 mg, 10 mg, 20 mg Filmtabletten
Belgium:	Tadalafil 5 mg, 10 mg, 20 mg filmomhulde tabletten
France:	TADALAFIL EG LABO 2,5 mg, 5 mg, 10 mg, 20 mg comprimé pelliculé
Germany:	Tadalafil STADA 2,5 mg, 5 mg, 10 mg, 20 mg Filmtabletten
Ireland:	Tadalafil Clonmel 10 mg, 20 mg film-coated tablets
Luxembourg:	Tadalafil Eurogenerics 5 mg, 10 mg, 20 mg comprimé pelliculé
Spain:	Tadalafilo STADAGEN 2,5 mg, 5 mg, 10 mg, 20 mg comprimidos recubiertos con película EFG

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