

Package Leaflet: Information for the user

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

1. What Tadalafil is and what it is used for

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

Tadalafil **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 the ability of obtaining a hard erect penis suitable for sexual activity. 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.

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

Do not take Tadalafil 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.
- have 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.

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.

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 does not treat prostate cancer.

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 Tadalafil 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 {Invented name} and contact your doctor immediately.

Tadalafil should not be used as treatment of erectile dysfunction or benign prostatic hyperplasia by women because these are health problems specific to men.

Children and adolescents

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

Other medicines and Tadalafil

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

Do not take Tadalafil 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 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.

Pregnancy, breastfeeding and Fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not take tadalafil when pregnant, unless it is strictly necessary and you have discussed this with your doctor.

Breastfeeding

Do not breastfeed while taking these tablets as it is not known if the medicine passes into human breast milk. Ask your doctor or pharmacist for advice before taking any medicine while pregnant or breastfeeding.

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 contains lactose:

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

3. How to take Tadalafil

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

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

Do not take Tadalafil more than once a day.

For the treatment of erectile dysfunction

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 2.5mg tablet.

Do not take Tadalafil more than once a day.

When taken once a day Tadalafil allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Tadalafil may be useful to men who anticipate having sexual activity two or more times per week.

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, avoid excessive drinking (blood alcohol level of 0.08 % or greater), since this may increase the risk of dizziness when standing up.

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.

If you take more Tadalafil than you should

If you or anyone else takes more tablets than they should, tell your doctor or go to a hospital immediately, taking the medicine or pack with you. You may experience side effects described in section 4.

If you forget to take Tadalafil

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 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).
- priapism, a prolonged and possibly painful erection after taking Tadalafil (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, 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 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 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 and sudden cardiac death.

The side effects dizziness have 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

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 blister or carton after EXP.

The expiry date refers to the last day of that month.

This medicine does not require any special temperature 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 contains

- The **active substance** is tadalafil.
Each film-coated tablet contains 5 mg tadalafil.

- The **other ingredients** are:

Tablet core:

Lactose monohydrate, Croscarmellose sodium, Hypromellose, cellulose microcrystalline, Sorbitan stearate and Magnesium stearate

Film-coating:

Lactose monohydrate, Hypromellose, Titanium dioxide (E171), Triacetin, Talc and Iron oxide yellow (E172).

What Tadalafil look like and contents of the pack

Light yellow, capsule shaped, approximately 8.6 mm in length and 4.8 mm in width, biconvex, bevelled edged, film coated tablet, debossed with "T 5" on one side and plain on other side.

Tadalafil is available in PVC/PE/PVdC clear Aluminium blister.

Pack sizes: 14, 28, 30, 84 or 90 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

United Kingdom

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

Ireland

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

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3526 KV Utrecht,
The Netherlands

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola, PLA 3000
Malta

Accord Healthcare Polska Sp.z o.o.,

ul. Lutomińska 50,95-200 Pabianice, Poland

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

Country	Invented Name
United Kingdom	Tadalafil 2.5/5/10/20 mg Film-coated Tablets
Austria	Tadalafil Accord 5/10/20 mg Filmtabletten
Bulgaria	Tadalafil Акорд 2.5/5/10/20 мг филмирани таблетки
Cyprus	Tadalafil Accord 5/20 mg Film-coated Tablets
Czech	Tadalafil Accord 5/20 mg potahované tablety
Germany	Tadalafil Accord 5/20 mg Filmtabletten
Denmark	Tadalafil Accord
Estonia	Tadalafil Accord
Finland	Tadalafil Accord 2.5/5/10/20 mg tabletti kalvopäällysteinen/ filmdragerad tablet
Italy	Tadalafil Accord
Ireland	Tadalafil 5/10/20 mg Film-coated Tablets
Lithuania	Tadalafil Accord 5/10/20 mg plėvele dengtos tabletės
Latvia	Tadalafil Accord 20 mg apvalkotās tabletes
Netherlands	Tadalafil Accord 5/10/20 mg, filmomhulde tabletten
Norway	Tadalafil Accord
Poland	Tadalafil Accord
Sweden	Tadalafil Accord 2.5/5/10/20 mg filmdragerad tablet
Slovakia	Tadalafil Accord 2,5 mg/ 5 mg/ 10 mg/ 20 mg filmom obalené tablety
France	TADALAFIL ACCORD 2,5 mg,/ 5 mg,/ 10 mg,/ 20 mg, comprimé pelliculé

This leaflet was revised in 11/2019.