

Package Leaflet: Information for the user

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 is and what it is used for
2. What you need to know before you take Tadalafil
3. How to take Tadalafil
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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:

- **Erectile dysfunction in adult men:**
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.
- **Pulmonary arterial hypertension in adults**
It works by helping the blood vessels around your lungs relax, improving the flow of blood into your lungs. The result of this is an improved ability to do physical activity.

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:

- any heart problems other than your pulmonary hypertension.
- problems with your blood pressure.
- any hereditary eye disease.
- 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, or your vision is distorted, dimmed while you are taking Tadalafil, 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 Tadalafil and contact your doctor immediately.

Tadalafil should not be used as treatment of erectile dysfunction 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:

- bosentan (another treatment for pulmonary arterial hypertension)
- nitrates (for chest pain)
- 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 been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Tadalafil 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

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.

To treat erectile dysfunction

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

You may take a Tadalafil tablet at least 30 minutes before sexual activity.

Tadalafil may still be effective up to 36 hours after taking the tablet.

Do not take Tadalafil 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.

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 pulmonary arterial hypertension

Tadalafil is supplied as a 20 mg tablet. The usual dose is two 20 mg tablets taken once a day. You should take both tablets at the same time, one after the other. If you have a mild or moderate liver or kidney problem, your doctor may advise you to take only one 20 mg tablet per 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 stop taking Tadalafil

For the treatment of pulmonary arterial hypertension do not stop taking your tablets, unless advised otherwise by your doctor.

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), distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

Other side effects have been reported and these are listed below, separated by indication:

Side effects in erectile dysfunction

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.
- distorted, dimmed, blurred central vision or sudden decrease of vision (frequency not known).

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.

Side effects in pulmonary arterial hypertension

Very common (may affect more than 1 in 10 people)

- headache, flushing, nasal and sinus congestion (blocked nose), nausea, indigestion (including abdominal pain or discomfort), muscle aches, back pain and pain in the extremity (including limb discomfort)

Common (may affect up to 1 in 10 people)

- blurred vision, low blood pressure, nosebleed, vomiting, increased or abnormal uterine bleeding, swelling of the face, acid reflux, migraine, irregular heartbeat and fainting.

Uncommon (may affect up to 1 in 100 people)

- seizures, passing memory loss, hives, excessive sweating, penile bleeding, presence of blood in semen and/or urine, high blood pressure, fast heart rate, sudden cardiac death and ringing in the ears.

Most but not all of those men reporting fast heart rate, irregular heartbeat, heart attack, stroke and sudden cardiac death had known heart problems before taking tadalafil. It is not possible to determine whether these events were related directly to 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.

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 20 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

Yellow, capsule shaped, approximately 14.3 mm in length and 7 mm in width, biconvex, bevelled edged, film coated tablet, debossed with "T 20" on one side and plain on other side.

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

Pack sizes: 2, 4, 8, 12, 14, 28, 30, 56 or 60 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Accord Healthcare B.V.,
Winthontlaan 200,

3526 KV Utrecht,
The Netherlands

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

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicine
United Kingdom (Northern Ireland)	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

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