

Package leaflet: Information for the user

Tadalafil Teva 10 mg film-coated tablet
Tadalafil Teva 20 mg film-coated tablet
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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Tadalafil Teva is used for treatment of erectile dysfunction and /or urinary symptoms associated with benign prostatic hyperplasia. Tadalafil Teva contains the active substance tadalafil which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Erectile dysfunction

Tadalafil Teva 10 mg and 20 mg 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 Teva has been shown to significantly improve the ability of obtaining a hard erect penis suitable for sexual activity. Following sexual stimulation Tadalafil Teva 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 Teva will not help you if you do not have erectile dysfunction.

It is important to note that Tadalafil Teva 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 (see section 3).

2. What you need to know before you take Tadalafil Teva

Do NOT take Tadalafil Teva 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 Teva has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure tell your doctor (see section “Other medicines and Tadalafil Teva”).
- 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 before taking Tadalafil Teva.

If you are being treated for erectile dysfunction

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 Teva 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, STOP taking Tadalafil Teva and contact your doctor immediately.

Tadalafil Teva is not intended for use by women.

Children and adolescents

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

Other medicines and Tadalafil Teva

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

Do NOT take Tadalafil Teva if you are already taking any form of nitrates (See ‘Do NOT take Tadalafil Teva).

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

Information on the effect of alcohol is in section 3. Grapefruit juice may affect how well Tadalafil Teva 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 Teva in clinical studies have reported dizziness. Check carefully how you react to the tablets before driving or using machines.

Tadalafil Teva 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.

3. How to take Tadalafil Teva

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

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

Tadalafil Teva 10 mg and 20 mg for erectile dysfunction

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. Tadalafil Teva tablets are for oral use.

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

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

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

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

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

If you take more Tadalafil Teva than you should

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

If you forget to take Tadalafil Teva

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 Teva 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).
- prolonged and possibly painful erection after taking Tadalafil Teva (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 (seen in 1 to 10 in every 100 patients)

- headache
- back pain
- muscle aches
- pain in arms and legs
- facial flushing
- nasal congestion
- indigestion and reflux.

Uncommon (seen in 1 to 10 in every 1,000 patients)

- dizziness
- stomach ache
- blurred vision
- eye pain
- increased sweating
- difficulty in breathing
- penile bleeding
- presence of blood in semen and/or urine
- pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure
- nose bleeds and ringing in the ears.

Rare (seen in 1 to 10 in every 10,000 patients)

- fainting
- seizures
- passing memory loss
- swelling of the eyelids, red eyes, sudden decrease or loss of hearing and hives (itchy red welts on the surface of the skin).

Heart attack and stroke have also been reported rarely in men taking Tadalafil Teva. 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 Teva 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.

The side effects dizziness and diarrhoea have been reported more frequently in men over 75 years of age taking Tadalafil Teva.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Teva

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 Teva contains

- The active substance is tadalafil.
Each 10 mg tablet contains 10 mg of tadalafil.
Each 20 mg tablet contains 20 mg of tadalafil.
- The other ingredients are lactose monohydrate, sodium laurilsulfate, povidone, crospovidone and sodium stearyl fumarate.
- The tablet coating is made of poly(vinyl alcohol), macrogol, titanium dioxide (E171), talc and iron oxide yellow (E172).

What Tadalafil Teva looks like and contents of the pack

Tadalafil Teva 10 mg ochre to yellow, oval shaped film coated tablet. On one side scored and debossed with "1" on the left side of the score and with "0" on the right side of the score. The other side of the tablet is plain. Length: 11.1 mm, width: 6.4 mm.
The tablet can be divided into equal doses.

Tadalafil Teva 20 mg ochre to yellow, oval shaped film coated tablet. On one side scored and debossed with “2” on the left side of the score and with “0” on the right side of the score. The other side of the tablet is plain. Length: 14.0 mm, width: 8.0mm.
The tablet can be divided into equal doses.

Tadalafil Teva 10 mg is available in pack sizes of 4 or 28 film-coated tablets in blisters or 4x1 or 24x1 film-coated tablets in perforated unit-dose blisters.
Tadalafil Teva 20 mg is available in pack sizes of 2, 4, 5, 8, 10, 12, 15, 28 or 56 film-coated tablets in blisters or 4x1, 12x1 or 24x1 film-coated tablets in perforated unit-dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer

TEVA Gyógyszergyár Zrt. (TEVA Pharmaceutical Works Private Limited Company)
Debrecen, Pallagi út 13,
H-4042
Hungary

TEVA UK Ltd
Brampton Road, Hampden Park, Eastbourne, East Sussex,
BN22 9AG
United Kingdom

Teva Pharma B.V.
Swensweg 5, Haarlem
2031 GA
The Netherlands

Teva Operations Poland Sp. z.o.o
Ul. Mogilska 80. , Krakow
31-546
Poland

TEVA PHARMA S.L.U.
C/C, n. 4, Poligono Industrial Malpica, Zaragoza
50016
Spain

Merckle GmbH
Ludwig-Merckle-Straße 3, Blaubeuren
89143
Germany

Merckle GmbH
Graf-Arco-Str. 3, Ulm
89079

Germany

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)
Prilaz baruna Filipovica 25, Zagreb
10000
Croatia

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

Austria	Tadalafil ratiopharm 2.5 mg, 5 mg, 10 mg, 20 mg Filmtabletten
Belgium	Tadalafil Teva 2,5 mg, 5 mg, 10 mg, 20 mg filmomhulde tabletten
Czech Republic	Tadalafil Teva 2,5 mg, 5 mg, 10 mg, 20 mg potahované tablety
Germany	Tadalafil-ratiopharm 2,5mg, 5 mg, 10 mg, 20 mg Filmtabletten
Denmark	Tadalafil Teva
Spain	Tadalafilo Teva 2.5 mg, 5 mg, 10 mg, 20 mg comprimidos recubiertos con película EFG
Finland	Tadalafil ratiopharm 2.5 mg, 5 mg, 10 mg, 20 mg tabletti, kalvopäällysteinen
France	Tadalafil Teva 2.5 mg, 5 mg, 10 mg, 20 mg comprimé pelliculé
Croatia	Tadalafil Pliva 2,5 mg, 5 mg, 10 mg, 20 mg filmom obložene tablete
Ireland	Tadalafil Teva 10 mg, 20 mg Film-coated Tablets
Iceland	Tadalafil ratiopharm 2.5 mg, 5 mg, 10 mg, 20 mg filmuhúðaðar töflur
Italy	Tadalafil Teva
Lithuania	Tadalafil-ratiopharm 2,5mg, 5 mg, 10 mg, 20 mg Filmtabletten
Netherlands	Tadalafil Teva 2.5 mg, 5 mg, 10 mg, 20 mg filmomhulde tabletten
Norway	Tadalafil Teva 2,5 mg, 5 mg, 10 mg, 20 mg filmdrasjerte tabletter
Poland	Tadalafil Teva
Portugal	Tadalafil Teva 2,5 mg, 5 mg, 10 mg, 20 mg comprimidos revestidos por película
Romania	TADALAFIL TEVA 2,5 mg, 5 mg, 10 mg, 20 mg comprimate filmate
Sweden	Tadalafil Teva 2,5 mg, 5 mg, 10 mg, 20 mg filmdragerade tabletter
United Kingdom	Tadalafil 2.5 mg, 5 mg, 10 mg, 20 mg Film-coated Tablets

This leaflet was last approved in September 2016