

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Tadalafil Teva 20 mg Tablets

Composition:

Each tablet contains:
Tadalafil 20 mg
to be used "on demand"

For information about inactive ingredients, see section 2 – 'Important information about some of this medicine's ingredients' and section 6 – 'Additional information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Tadalafil Teva is indicated for the treatment of erectile dysfunction in men.

Therapeutic group: Urologicals, drugs used in erectile dysfunction.

Tadalafil Teva contains the active ingredient tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors (PDE5 inhibitors).

Erectile dysfunction 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 to get a hard erect penis suitable for sexual activity.

Following sexual stimulation, Tadalafil Teva works by relaxing the blood vessels in your penis, 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.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient tadalafil or to any of the other ingredients that this medicine contains (see section 2 – 'Important information about some of this medicine's ingredients' and section 6 – 'Additional information').
- you 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 effect of these medicines. If you are taking any form of nitrate or are unsure, tell your doctor.
- you have serious heart disease or had a heart attack within the past 90 days.
- you recently had a stroke within the last 6 months.
- you have low blood pressure or uncontrolled high blood pressure.
- you ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".
- you are taking riociguat. This medicine 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 attributable to blood clots). PDE5 inhibitors, such as Tadalafil Teva, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure, tell your doctor.

This medicine is not intended for use in patients under 18 years of age or in women.

Special warnings regarding use of this medicine

Talk to your doctor before taking Tadalafil Teva. 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 consult with your doctor.

Before taking the tablets, tell your doctor if:

- you have sickle cell anemia (an abnormality of red blood cells).
- you have multiple myeloma (cancer of the bone marrow).
- you have leukemia (cancer of the blood cells).
- you have any deformation of your penis.
- you have a serious liver problem.
- you have 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.

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

Decreased or sudden hearing loss has been observed in some patients taking tadalafil. Although it is not known if the event is directly related to the use of tadalafil, if you experience decreased or sudden hearing loss, stop using Tadalafil Teva and contact your doctor immediately.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Do not take Tadalafil Teva if you are taking nitrates.

Some medicines may be affected by Tadalafil Teva or they may affect how well Tadalafil Teva works. 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 human immunodeficiency virus (HIV) infection.
- phenobarbital, phenytoin and carbamazepine (anticonvulsant medicines).
- rifampicin, erythromycin, clarithromycin or itraconazole.
- other treatments for erectile dysfunction.

Using this medicine and food and beverages

Tadalafil Teva tablets are for oral use in men only. Swallow the tablet or half tablet with some water. Tadalafil Teva can be taken with or without food. Grapefruit juice may affect how well Tadalafil Teva works and should be taken with caution. Talk to your doctor for further information.

Using this medicine and alcohol consumption

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 alcohol consumption (blood alcohol level of 0.08% or higher), since this may also increase the risk of dizziness when standing up after lying down.

Fertility

In tests conducted in dogs, reduced sperm production was found. A reduction in sperm production has also been observed in some men. These effects are unlikely to harm fertility.

Driving and using machines

Some men taking tadalafil in clinical studies have reported dizziness. Check carefully how you respond to the tablets before driving or using machines.

Important information about some of this medicine's ingredients

Tadalafil Teva contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before using this medicine.

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

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The standard dose for the treatment of erectile dysfunction in men, unless otherwise prescribed by your doctor:

The recommended starting dosage is 10 mg tadalafil (half a Tadalafil Teva 20 mg tablet) before sexual activity. If the effect of this dosage is too weak, your doctor may increase the dosage to 20 mg tadalafil (one Tadalafil Teva 20 mg tablet).

Your doctor may have prescribed you a dosage of 20 mg tadalafil (one Tadalafil Teva 20 mg tablet) as they decided that the recommended dosage of 10 mg is too weak for you.

Take Tadalafil Teva at least 30 minutes before sexual activity.

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

Do not take Tadalafil Teva more than once a day. Tadalafil Teva is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

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.

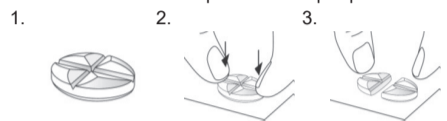
Do not exceed the recommended dose.

Splitting / crushing / chewing

Tadalafil Teva 20 mg tablets have a score line. When necessary, the tablet may be split according to the instructions below:

Instructions for splitting the tablet in half (each half tablet contains 10 mg tadalafil for use "as necessary"):

1. Place the tablet on a hard and flat surface (e.g., a table) with the score lines facing up.
2. Place thumbs (or index fingers) of both hands on both sides of the tablet's shorter score line at the same time.
3. Use your thumbs (or index fingers) to push down hard for a short time on the outer left and right sides of the tablet until it is split into two equal parts.



There is no information about crushing or chewing the tablet.

In addition, there is no information regarding the use of the preparation through a nasogastric tube.

If you have accidentally taken a higher dose

If you have accidentally taken a higher dose, you should contact your doctor. You may experience side effects as listed in section 4 – 'Side effects'.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine

If you forgot to take the medicine at the scheduled time, take the medicine as soon as you remember, but do not take a double dose to make up for a forgotten dose. You should not take Tadalafil Teva more than once a day.

Follow the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Tadalafil Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them. These side effects are normally mild to moderate.

Stop treatment and consult your doctor immediately if you suffer from:

- an allergic reaction including skin rashes (frequency uncommon).
- chest pain - do not use nitrates and seek immediate medical assistance (frequency uncommon).
- prolonged and possibly painful erection after taking Tadalafil Teva (priapism) (frequency rare). If you have such an erection, which lasts continuously for more than 4 hours, 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 that have been reported:

Common side effects (seen in 1-10 in 100 users): Headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion and indigestion.

Uncommon side effects (seen in 1-10 in 1,000 users):

Dizziness, stomach ache, nausea, vomiting, heartburn, 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 or buzzing in the ear (tinnitus), swelling of the hands, feet or ankles and feeling tired.

Rare side effects (seen in 1-10 in 10,000 users):

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 reported in rare cases.

Some 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 rash, 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).

Dizziness has been reported more frequently in men over 75 years of age taking tadalafil. Diarrhea has been reported more frequently in men over 65 years of age taking tadalafil.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the carton. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.
- Do not dispose of any medicine via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, povidone, crospovidone, polyvinyl alcohol, sodium stearyl fumarate, sodium laurilsulfate, PEG 3350, titanium dioxide, talc, iron oxide yellow.

What the medicine looks like and contents of the package:

A film-coated brown-yellow to yellow oval tablet. On one side of the tablet are score lines for cutting the tablet into four equal parts. "20" is printed on the other side of the tablet.

A package of Tadalafil Teva 20 mg contains 1, 4 or 8 tablets.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in December 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
154.90.34233