PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Tadalis Teva 20 mg

Tablets

Composition:
Each tablet contains:
Tadalafil 20 mg
To be used "as needed"
For information about inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Important information about Tadalis Teva:
- Tadalis Teva may cause a sudden decrease in blood pressure when taken with nitrates. Consult the doctor or pharmacist if you are unsure whether the preparations you are being treated with contain nitrates.
- A person who has taken Tadalis Teva and is in need of urgent medical care due to heart problems must inform the attending medical staff that he is taking the medicine, to avoid a situation in which he will be treated with nitrates!
- **If symptoms such as chest pain, dizziness or nausea occur during sexual activity, refer for medical assistance immediately.** Sexual activity involves a certain risk to heart patients, as it involves an extra strain on the heart.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tadalis Teva is intended for the treatment of erectile dysfunction in men, for obtaining and maintaining an erection.

Therapeutic group:
Tadalis Teva belongs to a group of preparations called phosphodiesterase type 5 (PDE5) inhibitors.

When taken for the treatment of erectile dysfunction, Tadalis Teva does not work in the absence of sexual stimulation.
Tadalis Teva enables an erection in response to sexual stimulation, starting 30 minutes after administration and up to 36 hours afterwards. The maximal dosage is one tablet per day, and the medicine is not recommended for regular, daily use.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient tadalafil or to any of the additional ingredients contained in the medicine (see section 6 – "Further information").
- You are taking a certain type of organic nitrate or the form that releases nitric oxide, such as amyl nitrite. This is a group of preparations ("nitrates") used in the treatment of angina pectoris ("chest pain"). Tadalis Teva could increase the effects of these preparations. If you are taking a certain type of nitrate or are unsure, tell your doctor.
- You are suffering from serious heart disease or have had myocardial infarction within the last 90 days.
- You have recently had a stroke that occurred within the last 6 months.
- You are suffering from low blood pressure or uncontrolled hypertension.
- You are suffering or have suffered in the past from vision loss as a result of NAION, a medical condition called "stroke of the eye".
- You are taking a medicine called riociguat. This is a medicine used to treat pulmonary hypertension, either primary or secondary to blood clots. PDE5 inhibitors, such as Tadalis Teva, may increase the blood-pressure-lowering effect of this medicine. If you are taking riociguat or are unsure, tell your doctor.

The medicine is not intended for use below the age of 18 or for women.

Special warnings regarding use of the medicine
You should know that sexual activity is a possible risk for heart patients as it requires an increased effort by the heart. If you have a heart problem you should consult your doctor.

Before beginning treatment with Tadalis Teva, tell the doctor if:
- You suffer from sickle cell anemia (abnormal red blood cells).
- Multiple myeloma (cancer of the bone marrow).
- Leukemia (cancer of the blood cells).
- There is a deformity in the structure of your penis.
- You suffer or have suffered in the past from a serious liver problem.
- You suffer or have suffered in the past from a serious kidney problem.
- You suffer from retinitis pigmentosa, a rare genetic eye disease.
- You suffer or have suffered in the past from impaired vision (see section 4 – "Side Effects").
- You have a stomach ulcer.
- You suffer from bleeding.

It is not known if Tadalis 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.

Warnings:
- **If the erection persists for more than 4 hours, refer to a doctor immediately.**
- If you experience a sudden reduction/loss of vision, stop the use of Tadalis Teva and contact your doctor immediately.
- Decreased hearing or sudden hearing loss has been seen in some patients taking tadalafil. Even though the use of tadalafil cannot be directly implicated in this phenomenon, if you experience reduced hearing or sudden hearing loss, stop using Tadalis Teva and contact your doctor immediately.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- Nitrate preparations (see above section "Do not use the preparation if").
- Medicines belonging to the guanylate cyclase stimulator group (e.g., riociguat) – do not take concomitantly with Tadalis Teva. Concomitant use may cause a symptomatic decrease in blood pressure.
- Medicines from the alpha-blocker group (e.g., doxazosin), used for the treatment of an enlarged prostate gland, or other medicines used for the treatment of hypertension – concomitant use may increase the effect (decreasing blood pressure) of these medicines.
- Medicines from the 5-alpha-reductase inhibitors group (e.g., finasteride, used for the treatment of benign prostatic hyperplasia and for the treatment of hair loss in men) – since no official studies examining the effect of the combination between these two medicines have been conducted, inform the doctor if you are taking a medicine from this group.
- The following medicines may affect the levels of Tadalis Teva in the blood: certain oral antifungals (such as: ketoconazole and itraconazole); macrolide antibiotics (such as: erythromycin and clarithromycin); medicines for the treatment of the AIDS virus that belong to the protease inhibitor group (such as: ritonavir and saquinavir); rifampicin (for the treatment of tuberculosis); phenobarbital (for sleep); phenytoin and carbamazepine (for the treatment of epilepsy); and theophylline (for the treatment of asthma).
- Do not use concomitantly with additional preparations for the treatment of erectile dysfunction.

Use of the medicine and food
Tadalis Teva may be taken with or without food.
Do not take Tadalis Teva at the same time as grapefruit juice, as the combination may affect Tadalis Teva levels in the blood.

Use of the medicine and alcohol consumption
Drinking alcohol may affect your ability to obtain an erection. Drinking alcohol may temporarily lower your blood pressure. Avoid excessive alcohol drinking (blood alcohol level of 0.08% or greater), as it may also increase the risk of dizziness when standing up from a lying position.

Driving and using machinery
Before driving or operating machinery, make sure that taking the medicine is not accompanied by dizziness.

Fertility
In testing carried out in dogs, a reduction in sperm production was found. A reduction in sperm production was also seen in some men. These effects are unlikely to lead to impaired fertility.

Important information about some of the ingredients of the medicine
Tadalis Teva contains lactose (lactose monohydrate). If you have been told by a doctor that you have an intolerance to certain sugars, consult with your doctor before taking the medicine.
This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dose and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.

The usual dose, unless otherwise instructed by the doctor, for the treatment of erectile dysfunction in men:
One tablet, at least 30 minutes prior to sexual contact. Do not take more than one tablet a day. May be taken at any time of day.
The effect of Tadalis Teva may last up to 36 hours. Since the effect of Tadalis Teva is maintained for more than one day, avoid daily use of the preparation.
It is important to emphasize that when taken for the treatment of erectile dysfunction, Tadalis Teva does not work in the absence of sexual stimulation. You and your partner should work to achieve sexual stimulation, just as you would if you were not taking a medicine for erectile dysfunction.

Do not exceed the recommended dose.
The Tadalis Teva 20 mg tablet has a score line; when necessary, the tablet can be halved.
There is no information regarding crushing or chewing the tablet. Additionally, there is no information regarding the use of the preparation in a nasogastric feeding tube.

If you forgot to take this medicine at the required time, take the medicine as soon as you remember, but do not take a double dose to make up for the forgotten dose.

If you accidentally take a higher dosage, refer to your doctor. You may experience side effects as described in section 4.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tadalis Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and contact a doctor immediately if you suffer from:
- A prolonged and painful erection after taking Tadalis Teva. If the erection persists for more than 4 hours, refer to a doctor immediately (occurring rarely).
- Sudden loss of vision (occurring rarely).
- An allergic reaction (including skin rash) (occurring infrequently).
- Chest pain – do not use nitrates and seek immediate medical care (occurring infrequently).

Side effects occurring frequently (occurred in 1-10 in 100 patients):
Headache, back pain, muscle pain, pain in arms and legs, facial flushing, nasal congestion, indigestion.
Dizziness occurred more frequently in men over 75 years of age who took Tadalis Teva. Diarrhea occurred more frequently in men over 65 years of age who took Tadalis Teva.

Side effects occurring infrequently (occurred in 1-10 in 1,000 patients):
Rashes, abdominal pain, vomiting, nausea, heartburn, blurred vision, eye pain, prolonged erection, nose bleeds, difficulty in breathing, pounding heartbeat sensation, rapid pulse, high blood pressure, low blood pressure, ringing or buzzing in the ear (tinnitus), dizziness, blood in the urine, peripheral edema, fatigue.

Side effects occurring rarely (occurred in 1-10 in 10,000 patients):
A partial, temporary or permanent decrease in vision or loss of vision in one or both eyes, a sudden decrease in hearing or loss of hearing, fainting, epileptic attack and passing memory loss, swelling of the eyelids, redness of the eyes, hives (red, itchy lesions on the skin), blisters or peeling skin, increased sweating, blood in the semen, bleeding from the penis.
Rare cases of cardiac infarction and stroke have been reported – in most cases, there was a preexisting heart problem before taking the medicine.

Side effects occurring rarely that did not occur in clinical trials:
Migraine, facial edema, severe allergic reaction manifested by edema of the face or throat, severe rash, disturbances in blood flow to the eyes, irregular pulse, angina pectoris and sudden cardiac death.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

<u>Reporting side effects</u>
Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe 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) that appears on the package. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.
- Consult your doctor or pharmacist on how to dispose of this medicine. This will help preserve the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the 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 the contents of the package:
Ochre to yellow, oval-shaped, film-coated tablet. One side of the tablet is scored, and debossed with "2" on the left side of the score line and with "0" on the right side of the score line. The other side of the tablet is plain.
The Tadalis Teva 20 mg package contains 1, 4 or 8 tablets.
Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address:
Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190, Petah-Tikva.

The leaflet was revised in September 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Tadalis Teva 20 mg – 154.90.34233

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