

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Sildenafil Teva 25 mg

Film-coated tablets
Composition

Each film-coated tablet contains:
Sildenafil (as citrate) 25 mg

Sildenafil Teva 50 mg

Film-coated tablets
Composition

Each film-coated tablet contains:
Sildenafil (as citrate) 50 mg

Sildenafil Teva 100 mg

Film-coated tablets
Composition

Each film-coated tablet contains:
Sildenafil (as citrate) 100 mg

For information about inactive ingredients and allergens: see section 2 under - '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.

This medicine is intended for adults over 18 years old and is not intended for women.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For treatment of impotence - erectile dysfunction.

Therapeutic group:

PDE5 (phosphodiesterase 5) enzyme inhibitor
Sildenafil causes dilation of blood vessels, thereby improving the blood flow into the penis during sexual stimulation.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (sildenafil) or to any of the other ingredients that this medicine contains (see section 6).
- You are intermittently or regularly taking nitrates, as the combination may lead to a dangerous fall in blood pressure. Tell your doctor if you are taking any of these medicines, which are often given for treatment of angina pectoris (chest pain). If you are not certain, ask the doctor or pharmacist.
- You are using any of the medicines known as nitric oxide donors, such as amyl nitrite, as the combination may lead to a dangerous fall in blood pressure.
- You are taking riociguat. This medicine is used to treat pulmonary hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Sildenafil Teva, have been proven to increase the hypotensive effect of this medicine. If you are taking riociguat or are unsure about this, tell the doctor.
- You suffer from a severe heart or liver disease.
- You have recently had a stroke or a heart attack, or if you suffer from low blood pressure.
- You suffer from a certain rare inherited eye disease (retinitis pigmentosa).
- You suffer or have suffered in the past from vision loss due to non-arteritic anterior ischemic optic neuropathy (NAION).

Special warnings regarding use of this medicine

Before using Sildenafil Teva, tell your doctor if:

- You suffer from sickle cell anemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow) or leukemia (cancer of the blood cells).
- You suffer from penis deformity or Peyronie's Disease (scoliosis of the penis).
- You have problems with your heart. Your doctor will check whether your heart can bear the additional strain associated with sexual intercourse.
- You suffer from a stomach ulcer or bleeding problems (such as hemophilia).
- You experience a sudden decrease or loss of vision; stop the treatment and contact your doctor immediately.
- Do not take Sildenafil Teva if you do not suffer from impotence (erectile dysfunction).
- Do not take Sildenafil Teva if you are a woman.

Patients with kidney or liver problems

Tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

The medicine is not intended for use under the age of 18 years.

Tests and follow-up

Before taking the medicine, the patient must undergo a comprehensive medical examination to ensure that the treatment is suitable for him and that he does not suffer from cardiovascular problems (heart and blood vessels), since sexual activity in itself involves a certain degree of cardiac effort.

Interactions with other medicines

A person who has taken Sildenafil Teva and requires any medical treatment must immediately report to the attending medical team that he has taken this medicine, in order to prevent a situation in which he will be treated with nitrates or other vasodilators.

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

Using Sildenafil Teva in combination with other medicines, especially medicines intended to treat chest pain, may be harmful. In the event of a medical emergency, you should inform your doctor, nurse or pharmacist that you have taken Sildenafil Teva and when you took it. Do not use Sildenafil Teva in combination with other medicines unless your doctor tells you that you can.

Do not use Sildenafil Teva if you are taking the following medicines:

- medicines called nitrates, as the combination with this type of medicine may lead to a dangerous decrease in your blood pressure. Consult your doctor if you are taking any of these medicines, which are usually used for the treatment of angina pectoris (chest pain).
- medicines known as nitric oxide donors such as amyl nitrite, as this combination too may lead to a dangerous decrease in your blood pressure.
- other medicines (oral or applied locally) for treating impotence (erectile dysfunction).
- riociguat
- pulmonary hypertension treatments that contain sildenafil or other PDE5 inhibitors.

Other medicines:

- Cimetidine (to reduce stomach acidity), ketoconazole (antifungal), erythromycin (antibiotic).
- Medicines called protease inhibitors, for example for the treatment of AIDS (HIV) (such as saquinavir, ritonavir) since they may increase the concentration of Sildenafil Teva in the blood. Your doctor may prescribe you the lowest dose.
- Medicines of the alpha-blockers group such as doxazosin (for the treatment of hypertension or prostate enlargement) – due to the concern of a decrease in blood pressure. Combination of this medicine with Sildenafil Teva may cause a feeling of dizziness, which can be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildenafil Teva with alpha blockers. This is most likely to happen within 4 hours after taking Sildenafil Teva. To reduce the chance that these symptoms might happen, you should be treated with a regular daily dosage of an alpha blocker before taking Sildenafil Teva. Your doctor may prescribe you the lowest dose.
- Medicines that contain sacubitril/valsartan which are used to treat heart failure.

Using this medicine and food

The medicine can be taken with or without food. However, the onset of the medicine's effect may be delayed after a heavy meal.

Using this medicine and alcohol consumption

Alcohol consumption may temporarily impair erectile function. To achieve the maximal effect of the medicine, you are advised not to drink excessive amounts of alcohol before taking the medicine.

Pregnancy and breastfeeding

This medicine is not intended for women.

Driving and using machines

Sildenafil Teva may cause dizziness and affect vision. You must pay attention to how you react to the medicine before you drive or operate machines.

Important information about some of this medicine's ingredients

This medicine contains less than 23 mg per tablet and is therefore considered 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 recommended dose is usually: one tablet about an hour before sexual intercourse.

Do not take more than one tablet per day. Do not exceed the recommended dose.

Sildenafil Teva will only help you to get an erection if you are sexually stimulated. The time it takes the medicine to start working varies from person to person, but it normally takes about half an hour to one hour. You may find that the medicine takes longer to start working if you take it with a heavy meal. If you feel that this medicine is too weak or too strong for you, consult your doctor or pharmacist.

If Sildenafil Teva does not help you to get an erection, or if your erection does not last long enough for you to complete full sexual intercourse, ask your doctor for advice.

Do not chew. Swallow the tablet whole with some water.

Do not halve the tablet, as there is no score line on it.

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

If you have taken an overdose, you may experience an increase in side effects and their severity.

Doses above 100 mg do not increase the efficacy of the medicine.

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 Sildenafil 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.

The side effects reported in association with the use of sildenafil are usually mild to moderate and last for a short time period.

Stop taking this medicine and contact your doctor immediately if any of the following serious side effects occur:

- An allergic reaction – **an uncommon side effect** (affects 1–10 in 1,000 users); the symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pain – **an uncommon side effect**. If this happens to you during or after sexual intercourse, get in a semi-sitting position and try to relax. **Do not take nitrates to treat chest pain.**
- Prolonged and sometimes painful erection – **a rare side effect** (affects 1–10 in 10,000 users). If you experience an erection which lasts for more than 4 hours, contact a doctor immediately.
- Sudden decrease or loss of vision – **a rare side effect**.
- Severe skin reactions – **a rare side effect**. The symptoms may include severe peeling and swelling of the skin, blisters in the mouth, genitals, around the eyes, and fever.
- Fits or seizures – **a rare side effect**.

Additional side effects

Very common side effects (affect more than one in ten users):
Headache.

Common side effects (affect 1–10 in 100 users):

Dizziness, redness of the face, indigestion, nasal congestion, seeing colors, blurred vision, vision disturbances, nausea, hot flushes (a sudden feeling of heat in the upper body).

Uncommon side effects (affect 1–10 in 1,000 users):

Vomiting, skin rash, eye irritation/pain, red eyes, sensitivity to light, seeing flashes of light, visual brightness, watery eyes, rapid or pounding heartbeat, hypertension, low blood pressure, muscle pain, sleepiness, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or congested sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and nasal congestion), upper abdominal pain, gastroesophageal reflux disease (symptoms include heartburn), feeling tired, presence of blood in urine, pain in the extremities, nosebleed, feeling hot.

Rare side effects (affect 1–10 in 10,000 users):

Fainting, stroke, heart attack, heart rate disorders, sudden decrease or loss of hearing, temporary decrease in blood flow to parts of the brain, feeling constriction in the throat, numb mouth, bleeding at the back of the eye, double vision, reduced visual acuity, abnormal sensation in the eye, swelling of the eye or eyelid, seeing small particles or spots, seeing halos around lights, dilation of the pupils, discoloration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, irritability.

Side effects based on post-marketing reports:

Unstable angina and sudden death have been reported rarely. Most, but not all, of the men who experienced these side effects suffered from heart problems before taking this medicine. It is impossible to determine whether these effects were directly related to the use of the medicine.

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 side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' 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 package. The expiry date refers to the last day of that month.
- Store in a dry place, below 25°C.**

6. ADDITIONAL INFORMATION

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

Microcrystalline cellulose (Avicel PH-102), dibasic calcium phosphate anhydrous, croscarmellose sodium, magnesium stearate, Opadry II white 85F18422.

Opadry II white 85F18422 contains: polyvinyl alcohol-part hydrolyzed, titanium dioxide, macrogol/PEG 3350, talc.

What the medicine looks like and contents of the package:

- Sildenafil Teva 25 mg: a white, oval, film-coated tablet. One side is imprinted with S25 and the other side is blank.
 - Sildenafil Teva 50 mg: a white, oval, film-coated tablet. One side is imprinted with S50 and the other side is blank.
 - Sildenafil Teva 100 mg: a white, oval, film-coated tablet. One side is imprinted with S100 and the other side is blank.
- Package sizes: 2, 4, 8, or 12 film-coated tablets packed in blister trays.
Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

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

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

Sildenafil Teva 25 mg: 147.84.33479

Sildenafil Teva 50 mg: 147.85.33480

Sildenafil Teva 100 mg: 147.86.33474