

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Viagra™ 25, 50, 100 mg, film-coated tablets

Each tablet contains sildenafil (as citrate) 25, 50, 100 mg, respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think 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 the medicine intended for?

For treatment of impotence – erectile dysfunction.

Therapeutic group: PDE5 (phosphodiesterase 5) enzyme inhibitor

Sildenafil causes blood vessels to dilate, thus improving blood flow into the penis during sexual arousal.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (sildenafil), or to any of the other ingredients this medicine contains (see section 6).
- You are taking medicines called nitrates, as the combination may lead to a dangerous fall in blood pressure. Tell the 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 **Viagra**, have been proven to increase the hypotensive effect of this medicine. If you are taking riociguat or are unsure about that, tell the doctor.
- You suffer from a severe heart or liver problem.
- 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 (such as retinitis pigmentosa).
- You have ever had loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION).

Special warnings regarding the use of the medicine

Before the treatment with Viagra, tell the doctor if:

- You suffer from sickle cell anemia (an abnormality of red blood cells), leukemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- You suffer from a deformity of the male sex organ (penis) or from Peyronie's disease (curvature of the penis).
- You have heart problems. The doctor will check whether your heart can take the additional strain involved in having sexual intercourse.

- You suffer from a stomach ulcer or from bleeding problems (such as hemophilia).
- You experience a sudden decrease or loss of vision, stop the treatment and refer to a doctor immediately.

Do not take **Viagra** if you do not suffer from impotence (erectile dysfunction).

Do not take **Viagra** if you are a woman.

Patients with kidney or liver problems

You should tell the doctor if you suffer from kidney or liver problems. The doctor may decide on a lower dosage for you.

Children and adolescents

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

Tests and follow-up

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

Drug interactions

A person who has taken **Viagra** and needs any medical treatment must immediately inform the treating medical staff that he has taken this medicine, to prevent a situation in which he is given treatment with nitrates or other blood vessel dilators.

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

Viagra in combination with other medicines may be harmful, especially medicines intended for treatment of chest pain. In case of a medical emergency, you should inform the doctor, pharmacist or nurse that you have taken **Viagra** and when you took it. Do not use **Viagra** in combination with other medicines, unless the doctor tells you that you can.

Do not use **Viagra** if you are taking the following medicines:

- Medicines called nitrates, as the combination with these medicines may lead to a dangerous fall in blood pressure. Consult the doctor if you are taking medicines of this type, usually used for treatment of angina pectoris (chest pain).
- Medicines known as nitric oxide donors such as amyl nitrite, as this combination may also lead to a dangerous fall in blood pressure.
- Other medicines (by oral or local administration) for treatment of impotence (erectile dysfunction).
- Riociguat
- Pulmonary hypertension treatments that contain sildenafil or other PDE5 inhibitors.

Additional medicines:

- Cimetidine (for reducing stomach acidity), ketoconazole (antifungal), erythromycin (an antibiotic).
- Medicines called protease inhibitors, for example for treatment of AIDS (HIV) (such as saquinavir, ritonavir) as they may increase the concentration of sildenafil in the blood. The doctor may prescribe you the lowest dosage.
- Medicines from the group of alpha blockers, such as doxazosin (for treatment of high blood pressure or for treatment of prostate enlargement). The combination with **Viagra** may cause a feeling of dizziness, which can be caused due to low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking **Viagra** with alpha blockers. This is most likely to happen within 4 hours after taking **Viagra**. To reduce the chance that these symptoms might happen,

you should be treated with a regular daily dosage of the alpha blocker before taking **Viagra**. The doctor may prescribe you the lowest dosage.

- Medicines containing sacubitril/valsartan which are used for treatment of heart failure.

Use of the medicine and food

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

Use of the medicine and alcohol consumption

Alcohol consumption may temporarily interfere with the appearance of an erection. To get the maximum benefit from the medicine, it is advised not to consume a large amount of alcohol before taking **Viagra**.

Pregnancy and breastfeeding

This medicine is not intended for use by women.

Driving and using machines

Viagra may cause dizziness and affect vision. You should be aware of how you react to the medicine before you drive or use machinery.

Important information about some of the ingredients of the medicine

Viagra 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.

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

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. **The generally accepted dosage is:** one tablet, about one hour before having sexual intercourse.

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

Viagra will help you achieve an erection only in a state of sexual arousal. The time it takes the medicine to start working varies from person to person, and it usually takes about half an hour to one hour. You may find that the medicine takes longer to start working if it is taken with a heavy meal.

If you feel that the medicine is too weak or too strong for you, consult the doctor or pharmacist.

If **Viagra** does not help you get an erection, or if the erection you get does not last long enough for you to complete full sexual intercourse, consult the doctor.

Method of administration

Do not crush, halve or chew. The medicine should be swallowed whole with some water.

If you have accidentally taken a higher dosage

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

If you have taken an overdose, you may suffer from 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 the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Viagra** 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.

Side effects reported during the use of **Viagra** are usually mild to moderate and last a short time.

Stop using the medicine and immediately refer to the doctor if any of the following serious side effects occur:

- An allergic reaction – **an uncommon effect** (an effect that occurs in 1-10 out of 1,000 users). Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pain – **an uncommon effect**. If this happens during or after sexual intercourse, sit 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** (an effect that occurs in 1-10 out of 10,000 users). If you experience an erection that lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision – **a rare side effect**.
- Serious skin reactions – **a rare side effect**. The symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Fits or seizures – **a rare side effect**.

Additional side effects

Very common side effects (effects that occur in more than 1 in 10 users): headache.

Common side effects (effects that occur in 1-10 out of 100 users): nausea, facial flushing, hot flushes (a sudden feeling of heat in your upper body), indigestion, seeing colors, blurred vision, visual disturbances, stuffy nose, dizziness.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users): vomiting, skin rash, eye irritation, red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, rapid or strong heartbeats, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastroesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

Rare side effects (effects that occur in 1-10 out of 10,000 users): fainting, stroke, heart attack, irregular heartbeat, temporary decrease in blood flow to parts of the brain, feeling of constriction of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discoloration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable, sudden decrease or loss of hearing.

Additional side effects reported post-marketing: unstable angina, sudden death have been reported rarely. Most, but not all, of the men who experienced these effects suffered from heart problems before taking this medicine. It cannot be determined whether there is a direct association between these effects and use of **Viagra**.

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

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Expiry date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store in a dry place, below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, hypromellose, lactose monohydrate, titanium dioxide (E171), glycerol triacetate, indigo carmine aluminum lake (E132)

What the medicine looks like and what the package contains:

Viagra 25 mg: blue, diamond shaped, film-coated tablet, imprinted with "Viagra" on one side and "VGR 25" on the other side.

Viagra 50 mg: blue, diamond shaped, film-coated tablet, imprinted with "Viagra" on one side and "VGR 50" on the other side.

Viagra 100 mg: blue, diamond shaped, film-coated tablet, imprinted with "Viagra" on one side and "VGR 100" on the other side.

Approved package sizes: 1, 2, 4, 8, 12 film-coated tablets. Not all package sizes may be marketed.

Revised in February 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Viagra 25 mg: 111-36-29459

Viagra 50 mg: 111-37-29460

Viagra 100 mg: 111-38-29461

Manufacturer and registration holder: Dexcel Pharma Technologies Ltd., 10 Hakidma St., Yokneam Illit 2069200, Israel