

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only. The format of this leaflet was determined by the Ministry of Health and its content was checked and approved.

**Viagra® 25 mg
Viagra® 50 mg
Viagra® 100 mg
Film-coated tablets**



**Each tablet contains:
Sildenafil Citrate (equivalent to Sildenafil)
25 mg, 50 mg, 100 mg**

A list of inactive ingredients and allergens in the preparation is in section 6.

Read this leaflet carefully in its entirety before using this 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 for your treatment. 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 the age of 18; it is not intended for women.

1. FOR WHAT IS THE MEDICINE INTENDED?
For the treatment of erectile dysfunction.

Therapeutic group:
PDE5 enzyme inhibitor, causes dilation of blood vessels thereby improving the blood flow into the penis during sexual stimulation.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- x you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine
- x you take organic nitrates, organic nitrites or nitric oxide donors in any form either regularly or intermittently (such as certain medicines for treating angina pectoris)
- x you are concomitantly taking guanylate cyclase stimulators (e.g., riociguat) for treating pulmonary hypertension
- x you suffer from a severe heart or liver disease
- x you have recently had a stroke or heart attack, or if you suffer from low blood pressure
- x you suffer from inherited eye disease (such as retinitis pigmentosa)
- x you suffered in the past from vision loss of the non-arteritic anterior ischaemic optic neuropathy (NAION) type

Do not use the medicine without consulting a doctor before commencing treatment:

- If you have an illness or deformity of your penis or Peyronie's Disease (scoliosis of the penis).
- If you suffer, or have suffered in the past, from impaired function of: the digestive system (e.g., ulcer), the blood system (e.g., frequent bleeding [hemophilia], coagulation, bone marrow, leukemia), the heart and/or blood vessels (myocardial infarction, cerebral stroke, life-threatening heart rate disturbance).
- If you suffer from sickle cell anemia, multiple myeloma (cancer of the bone marrow) or leukemia (cancer of the blood cells).
- If you suffer from decreased liver function (e.g., cirrhosis), severe renal failure, resting hypotension (blood pressure below 90/50), hypertension (blood pressure above 170/110), eye problems (e.g., retinitis pigmentosa) - it is not recommended to treat patients who have retinal damage.
- Patients above the age of 65 will be treated with a reduced initial dosage.

Special warnings regarding use of the medicine

- A person who has taken Viagra® and requires any type of medical treatment **must report immediately** 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 sensitive to any type of food or medicine, you must inform the doctor before taking the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

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

- you take organic nitrates, organic nitrites or nitric oxide donors in any form either regularly or intermittently (such as certain medicines for treating angina pectoris).
- Other medicines for treating erectile dysfunction - the combination with Viagra® is forbidden.
- Riociguat - to treat pulmonary hypertension - the combination with Viagra® is forbidden.

Other medicines:

- Cimetidine (to reduce stomach acidity),

ketoconazole (antifungal), erythromycin (antibiotic), HIV protease inhibitors for the treatment of AIDS (e.g., saquinavir, ritonavir), since they may increase the concentration of Viagra® in the blood.

- Alpha-blocker therapy such as doxazosin (for the treatment of hypertension) - for fear of a drop in blood pressure.

Use of the medicine and food

The medicine can be taken with or without food; however, after a heavy meal the effect of the medicine may be delayed.

Drinking alcohol may temporarily impair your ability to get an erection. To get the maximum benefit from 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 use of machinery

Viagra® may cause dizziness and affect vision. You must pay attention to how you react to the drug before you drive or operate machinery.

Important information about some of the ingredients of the medicine

If you are sensitive to lactose - the medicine contains lactose and may cause an allergy in people who are sensitive to lactose. Contact the doctor before using the medicine if you are sensitive to certain sugars.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure.

The medicine is intended for adults above 18 years of age.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally: one tablet about an hour before having sexual intercourse.

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

Do not chew! Swallow the medicine with a little water.

Tests and follow-up

Before taking the medicine, the patient must undergo a general 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.

If you took an overdose or if a child accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.

Dosage above 100 mg does not increase the efficacy of the medicine.

Do not take medicines in the dark! Check the label and the dose **each time** 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 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.

Stop treatment and refer to a doctor immediately in the case of:

Allergic reaction - the symptoms include wheezing, difficulty in breathing or dizziness, swelling of eyelids, face, lips or throat.

Chest pain during or after having sexual relations - get in a sitting position and try to relax. Do not take nitrates to treat chest pain.

Sudden complete or partial loss of vision in one eye or both eyes, a sudden reduction in hearing or hearing loss.

A prolonged erection that lasts for more than 4 hours (prolonged and sometimes painful erections have been reported after using Viagra®, at unknown frequency).

Severe skin reaction (unknown frequency) - the symptoms may include severe peeling and swelling of the skin, blisters in the mouth, genitals, around the eyes and fever.

Epileptic seizures (unknown frequency).

Additional side effects appearing very frequently:

Headache.

Additional side effects appearing frequently:

Dizziness, flushing of the face, digestive disturbances including diarrhea, stuffy nose, seeing colors, blurred vision, vision disturbances, nausea, hot flushes.

Additional side effects appearing infrequently:

Vomiting, rash, eye irritation/redness/pain, sensitivity to light, seeing flashes of light, visual brightness, excessive tearing, irregular or rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sensations, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the inner lining of the nose (including runny nose, sneezing and stuffy nose), upper abdominal pain, reflux (symptoms include heartburn), feeling tired, presence of blood in urine, pain in the extremities, nosebleed and feeling hot.

Additional side effects appearing rarely:

Fainting, stroke, heart attack, heart rate disturbances, sudden decrease or loss of hearing, temporary decreased blood flow to

parts of the brain, feeling of constriction of the throat, numb mouth, bleeding of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eyes, swelling of the eyes or eyelids, seeing small particles or spots, seeing halos around lights, dilated pupils, discoloration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, agitation.

Additional side effects whose frequency is unknown:

Unstable angina pectoris, sudden death. Most, but not all, of the men who suffered from these events, had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to use of the medicine.

If any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the 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 at a temperature below 30°C in a dry place.

6. FURTHER INFORMATION

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

Microcrystalline Cellulose, Calcium Hydrogen Phosphate, Croscarmellose Sodium, Magnesium Stearate.

The coating contains:

Hypromellose, Lactose Monohydrate, Glycerol Triacetate, Titanium Dioxide, Indigo Carmine Aluminum Lake.

What does the medicine look like and what are the contents of the package:

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

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

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

Manufacturer: FAREVA AMBOISE, Poce-sur-Cisse, France.

License holder: Pfizer PFE Pharmaceuticals Israel Ltd., Shenkar 9, Herzliya Pituach 46725. This leaflet was checked and approved by the Ministry of Health in January 2016.

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

Viagra® 25 mg: 111.36.29459.00

Viagra® 50 mg: 111.37.29460.00

Viagra® 100 mg: 111.38.29461.00