

Levitra® 5 mg Levitra® 10 mg Levitra® 20 mg Film-coated Tablets



Each film-coated tablet contains:
Vardenafil (as hydrochloride trihydrate) 5 mg or 10 mg or 20 mg

Inactive and allergenic ingredients: See 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 as treatment 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.

1) WHAT IS THE MEDICINE INTENDED FOR?

Levitra is intended for the treatment of erectile dysfunction in men.

At least one in ten adult men suffers, at times, from erectile dysfunction, namely, difficulty achieving or maintaining an erection. There may be physical or psychological causes, or a mixture of both factors. In any case, due to muscle and blood vessel changes, not enough blood reaches the penis to make it hard and keep it hard.

Therapeutic group: Levitra belongs to a group of medicines called PDE5 enzyme inhibitors.

Inhibition of the enzyme leads to relaxation of the muscles in the walls of the penile blood vessels, which enables blood to flow to the penis, thereby achieving an erection.

Levitra only works when there is sexual stimulation, and it allows the erection to last long enough to enable satisfactory sexual activity.

2) BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, vardenafil, or to any of the additional ingredients contained in the medicine. For a list of the inactive ingredients, see section 6 “Further Information”. Signs of an allergic reaction include a rash, itching, swollen face or lips and shortness of breath.
- You are taking medicines containing nitrates, such as glyceryl trinitrate to treat angina pectoris, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Levitra could seriously affect your blood pressure.
- You are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infections.
- You are over 75 years of age and are taking ketoconazole or itraconazole, antifungal medicines.
- You suffer from a severe heart or liver problem.
- You are undergoing kidney dialysis.
- You have recently had a stroke or heart attack (in the last half a year).
- You are suffering, or have suffered in the past, from low blood pressure.
- Your family has a history of degenerative eye diseases (e.g., *retinitis pigmentosa*).
- You have ever suffered from a condition involving loss of vision resulting from damage to the optic nerve due to insufficient blood supply, known as non-arteritic ischemic optic neuropathy (NAION).
- You are taking riociguat. This medicine is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and pulmonary hypertension secondary to chronic thromboembolic events (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 enzyme inhibitors, such as Levitra, have been observed to increase the hypotensive effects of riociguat. If you are taking riociguat or are unsure, tell your doctor.

Special warnings regarding use of the medicine:

Talk with the doctor or pharmacist before taking Levitra.

⚠ Before taking Levitra, tell your doctor if:

- You have a heart problem. Having sexual intercourse may be dangerous for you.
- You suffer from irregular heartbeat (*cardiac arrhythmia*) or inherited heart diseases affecting your ECG.
- You have a physical condition affecting the shape of your penis. This includes conditions called angulation, curvature of the penis (Peyronie's disease) and fibrosis (thickening and scarring of the erectile tissue).
- You suffer from an illness that can cause erections that do not go away (*priapism* - prolonged erection). These include sickle cell anemia, multiple myeloma and leukemia.
- You suffer from stomach ulcers (also called *gastric* or *peptic ulcers*).
- You have a bleeding disorder (such as *hemophilia*).
- You are using any other medicines for erection difficulties, including Levitra 10 mg orodispersible tablets (see also “Drug interactions” below).
- You experience a sudden decrease in or loss of vision, stop taking Levitra and contact your doctor immediately.

⚠ Children and adolescents

Levitra is not intended for use in children or adolescents under the age of 18.

⚠ Drug interactions

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

- Nitrates, medicines for the treatment of angina pectoris, or nitric oxide donors, such as amyl nitrite. Taking these medicines with Levitra could seriously affect your blood pressure. Talk to a doctor without taking Levitra.
- Medicine for the treatment of heart rhythm disturbances (arrhythmias), such as quinidine, procainamide, amiodarone or sotalol.
- Ritonavir or indinavir, medicines for the treatment of HIV (AIDS). Talk to a doctor without taking Levitra.
- Ketoconazole or itraconazole, antifungal medicines.
- Erythromycin or clarithromycin, macrolide antibiotics.
- Alpha-blockers, a type of medicine used to treat high blood pressure and enlargement of the prostate (e.g., *benign prostatic hyperplasia*).
- Riociguat for the treatment of certain types of pulmonary hypertension - do not take Levitra. For further details, see section 2 “Do not use the medicine if”.

Do not use Levitra film-coated tablets in combination with any other treatment for erectile dysfunction, including Levitra 10 mg orodispersible tablets.

⚠ Use of the medicine and food

Levitra can be taken with or without food, but preferably not after a heavy or high-fat meal, as this may delay the effect of the medicine.

Do not drink grapefruit juice when using Levitra. It can interfere with the usual effect of the medicine.

⚠ Use of the medicine and alcohol consumption

An alcoholic drink can worsen erection difficulties.

⚠ Pregnancy and breastfeeding

Levitra is not intended for use in women.

⚠ Driving and using machinery

Levitra could cause some people to feel dizzy or affect their vision. If you feel dizzy or if your vision is affected after taking Levitra, do not drive or operate any tools or machines.

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 dosage and treatment regimen.

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

The recommended dose is generally 10 mg.

Take one tablet about 25 to 60 minutes before having sexual activity.

With sexual stimulation, you may achieve an erection within 25 minutes to 4-5 hours after taking Levitra.

Do not take Levitra film-coated tablets with any other dosage forms of Levitra (e.g., Levitra 10 mg orodispersible tablets). **Do not take Levitra** more than once a day.

Tell your doctor if you think Levitra is too strong or too weak. The doctor may suggest switching to an alternative Levitra formulation with a different dosage, depending on the extent to which it affects you.

Do not exceed the recommended dosage.

Method of administration

Swallow one tablet with a glass of water.

There is no information regarding crushing/halving/chewing.

If you accidentally took a higher dosage, refer to the doctor.

Men who take too much Levitra may experience more side effects or may suffer from severe back pain.

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 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 Levitra may cause side effects in some users. Do not be alarmed by reading the list of side effects.

You may not suffer from any of them.

Most of the effects are mild or moderate.

Stop taking Levitra and contact your doctor immediately if you suffer from partial, sudden, temporary or permanent decrease in vision or loss of vision, in one or both eyes.

Additional side effects

There are reports of sudden decline in hearing or sudden loss of hearing.

Cases of sudden death, fast or altered heartbeat, heart attack, chest pain, and trouble in cerebral circulation (including temporary decrease in blood flow to parts of the brain and bleeding in the brain) have been reported in men taking vardenafil.

Most of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to vardenafil.

The chance of suffering from side effects is described by the following categories:

Very common side effects (may affect more than 1 in 10 users):

- Headache

Common side effects (may affect up to 1 in 10 users):

- Dizziness
- Flushing
- Blocked or runny nose
- Indigestion

Uncommon side effects (may affect up to 1 in 100 users):

- Swelling of skin and mucous tissue, including swollen face, lips or throat
- Sleep disorder
- Numbness and poor sense of touch
- Sleepiness
- Effects on vision, redness of the eye, effects on color vision, eye pain and discomfort, sensitivity to light
- Ringing in the ears, vertigo (rotatory dizziness)
- Fast heartbeat or pounding heart
- Shortness of breath
- Stuffy nose
- Acid reflux (heartburn), inflammation of the stomach lining (gastritis), abdominal pain, diarrhea, vomiting, nausea, dry mouth
- Raised levels of liver enzymes in your blood
- Rash, reddened skin
- Back pain or muscle pain, increase in blood of a muscle enzyme (*creatine phosphokinase*), muscle stiffness
- Prolonged erections
- Malaise

Rare side effects (may affect up to 1 in 1,000 users):

- Inflammation of the eyes (*conjunctivitis*)
- Allergic reaction
- Anxiety
- Fainting
- Amnesia
- Seizure
- Increased pressure in the eye (*glaucoma*), excessive tearing
- Effects on the heart (such as heart attack, changes in heartbeat or *angina pectoris*)
- High or low blood pressure
- Nosebleed
- Effect on results of blood tests to check liver function
- Sensitivity of the skin to sunlight
- Painful erections
- Chest pain
- Temporary decrease in blood flow to parts of the brain

Very rare side effects (may affect less than 1 in 10,000 users) or side effects **of unknown frequency** (side effects whose frequency cannot be estimated from the available data):

- Blood in the urine (*hematuria*)
- Penile bleeding (*penile hemorrhage*)
- Presence of blood in the semen (*hematospermia*)
- Sudden death
- Bleeding in the brain

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.

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://sideeffects.health.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept 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 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 25°C.
- Do not throw away any medicines via wastewater or the household waste bin. Ask your pharmacist how to throw away medicines no longer in use. These measures will help protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Cellulose microcrystalline, Crospovidone, Hypromellose, Magnesium stearate, Macrogol 400, Titanium dioxide (E171), Silica colloidal anhydrous, Ferric oxide-yellow (E172), Ferric oxide-red (E172).
- What does the medicine look like and what are the contents of the package:
Levitra 5 mg: orange to grayish-orange, film-coated, round tablets, with “BAYER” marked on their one side and “5” on the other side.
Levitra 10 mg: orange to grayish-orange, film-coated, round tablets, with “BAYER” marked on their one side and “10” on the other side.
Levitra 20 mg: orange to grayish-orange, film-coated, round tablets, with “BAYER” marked on their one side and “20” on the other side.

The tablets are supplied in trays (blisters), in packs of 2, 4, 8 or 12 tablets.

Not all package sizes may be marketed.

- Registration Holder and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.
- Manufacturer and address: Bayer Pharma AG, Leverkusen, Germany.
- This leaflet was checked and approved by the Ministry of Health in May 2016, and was updated in accordance with the Ministry of Health guidelines in February 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
 - Levitra 5 mg: 129 13 30773 00
 - Levitra 10 mg: 129 14 30774 00
 - Levitra 20 mg: 129 15 30775 00