

Package leaflet: information for the user

Levitra 5 mg film-coated tablets Vardenafil

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Levitra and what is it used for?

Levitra contains vardenafil, a medicine from the group of drugs called phosphodiesterase type 5 inhibitors. They are used for the treatment of erectile dysfunction in adult men, a condition that involves difficulty in getting or maintaining an erection.

At least one in ten men has problems with getting or maintaining an erection at some point. There can be physical or psychological causes, or a combination of both. Whatever the cause may be, due to muscle and blood vessel changes, there is not enough blood remaining in the penis to make and keep it erect.

Levitra only works if you are sexually stimulated. It reduces the effect of a natural chemical in the body that causes the erection to disappear. Levitra allows an erection to last long enough for satisfactory sexual intercourse.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6. Hypersensitivity reactions may include rash, itching, swollen face or lips, and shortness of breath.
- You have ever developed a severe skin rash or skin peeling, blistering and/or sores in the mouth after taking Levitra.
- You are taking medicines that contain nitrates, such as glyceryl trinitrate, for the treatment of angina pectoris, or medicines that release nitric oxide, such as amyl nitrite. Using these medicines together with Levitra can significantly change your blood pressure.

- You are taking ritonavir or indinavir, medicines used to treat human immunodeficiency virus (HIV) infection.
- You are over 75 years old and are taking ketoconazole or itraconazole, medicines for fungal infections.
- You have severe heart or liver problems.
- You are undergoing kidney dialysis.
- You have recently had a stroke or heart attack.
- You have or had low blood pressure.
- Your family has a history of degenerative eye disease (such as retinitis pigmentosa).
- You have ever had a condition where vision loss occurred due to damage to the optic nerve from insufficient blood supply, known as non-arteritic anterior ischemic optic neuropathy (NAION).
- You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (this is high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (this is high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as Levitra, have been shown to enhance the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure, contact your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Be extra careful with this medicine

- If you have heart problems. It may be dangerous for you to have sex.
- If you suffer from an irregular heartbeat (arrhythmias) or have a hereditary heart disease that affects the electrocardiogram (ECG).
- If you have a physical condition that affects the shape of the penis. These can be conditions such as angulation, Peyronie's disease, or fibrosis of the corpus cavernosum.
- If you have a condition that can cause erections that do not go away (priapism). These include sickle cell anemia, multiple myeloma, and leukemia.
- When you have a stomach ulcer (also known as a peptic ulcer).
- When you have a bleeding disorder (such as hemophilia).
- If you are using other treatments for erectile dysfunction, including Levitra orodispersible tablets (see section: Are you using any other medicines?).
- Severe skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, have been reported in connection with treatment with vardenafil. Stop using Levitra and seek immediate medical help if you notice any of the symptoms related to these severe skin reactions described in section 4.
- If you suddenly experience a reduction or loss of vision or if your vision is distorted or darkened while taking Levitra, stop taking Levitra and contact your doctor immediately.

Children and adolescents up to 18 years

Levitra is not intended for use by children and adolescents under 18.

Are you using any other medicines?

Are you using any other medicines besides Levitra, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Some medicines can cause problems, particularly:

- nitrates, medicines for angina, or substances that release nitric oxide, such as amyl nitrite ('poppers'). Using these medicines with Levitra can significantly change your blood pressure.
- medicines for the treatment of arrhythmias such as quinidine, procainamide, amiodarone, and sotalol.
- ritonavir or indinavir, medicines against HIV.
- ketoconazole or itraconazole, medicines against fungal infections.
- erythromycin or clarithromycin, macrolide antibiotics.
- alpha-blockers, a type of medicine used to treat high blood pressure or an enlarged prostate (such as benign prostatic hyperplasia).
- riociguat.

Do not use Levitra film-coated tablets together with another treatment for erectile dysfunction, including Levitra orodispersible tablets.

What should you pay attention to with food, drink, and alcohol?

- You can take Levitra with or without food but preferably not after a heavy or high-fat meal, as this may delay the onset of action.
- Do not drink grapefruit juice when using Levitra. This can affect the action of the medicine.
- Alcoholic beverages can worsen erectile dysfunction.

Pregnancy and breastfeeding

Levitra is not intended for use by women.

Driving and using machines

Levitra can cause dizziness or affect vision in some people. If you feel dizzy or have impaired vision after using Levitra, do not drive or use tools or machines.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist. The usual dosage is 10 mg.

Take a Levitra tablet approximately 25 to 60 minutes before sexual activity. With sexual stimulation, you may have an erection from about 25 minutes to 4-5 hours after taking Levitra.

- Swallow one tablet with a glass of water.

Do not use Levitra film-coated tablets together with other forms of Levitra.

Do not use Levitra more than once a day.

Inform your doctor if you think Levitra is too strong or not strong enough. He or she may suggest switching to another formulation of Levitra with a different dosage, depending on how well it works for you.

Have you used too much of this medicine?

Men who take too much Levitra may experience more side effects or may get severe back pain. If you take more Levitra than prescribed, inform your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everyone gets them. Most effects are mild to moderate.

Partial, sudden, temporary, or permanent reduction or loss of vision, or distorted, darkened, or blurred central vision in one or both eyes has been experienced by patients. If this happens, stop using Levitra and contact your doctor immediately. Sudden reduction or loss of hearing has been reported.

Cases of sudden death, rapid or altered heart rhythm, heart attack, chest pain, and problems in blood circulation in the brain (including temporary reduction of blood flow to parts of the brain and bleeding in the brain) have been reported in men using vardenafil. Most of the men who experienced these side effects had pre-existing heart problems before they took this medicine. It is not possible to determine whether these events were directly related to the use of vardenafil.

The likelihood of experiencing a side effect is described in the following categories:

Very common:

may occur in more than 1 in 10 users

- headache

Common:

may occur in up to 1 in 10 users

- dizziness
- flushing
- congested nose or runny nose
- indigestion

Sometimes:

may occur in up to 1 in 100 users

- swelling of skin and mucous membranes, including swollen face, lips, or throat
- sleep disorder
- numbness and reduced sense of touch
- drowsiness
- effects on vision, red eyes, effects on color vision, eye pain and discomfort, sensitivity to light
- tinnitus, vertigo
- rapid heartbeat or pounding heart
- shortness of breath
- nasal congestion
- heartburn, gastritis, abdominal pain, diarrhea, vomiting, nausea, dry mouth
- increased amount of liver enzymes in the blood
- skin rash, redness of the skin

- back or muscle pain, increased amount of a muscle enzyme in the blood (creatine phosphokinase), stiff muscles
- persistent erections
- malaise

Rarely:

may occur in up to 1 in 1,000 users

- eye inflammation (conjunctivitis)
- allergic reactions
- anxiety
- fainting
- memory loss
- seizures
- increased pressure in the eye (glaucoma), increased tearing
- effects on the heart (such as a heart attack, altered heart rate, or angina)
- high or low blood pressure
- nosebleed
- effect on blood test results for monitoring liver function
- sensitivity of the skin to sunlight
- painful erections
- chest pain
- temporary reduction of blood supply to parts of the brain

Very rarely or not known:

may occur in less than 1 in 10,000 users or the frequency cannot be determined based on the available data

- blood in the urine (hematuria)
- bleeding from the penis (penile bleeding)
- presence of blood in the semen (hematospermia)
- sudden death
- bleeding in the brain
- Reddish non-raised, disc-shaped or round spots on the trunk, often with central blistering, skin peeling, sores in the mouth, throat, nose, genitals, and eyes. These severe skin reactions may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Distorted, darkened or blurred central vision or sudden reduction of vision

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is vardenafil. Each tablet contains 5 mg vardenafil (as hydrochloride).
- The other substances in this medicine are:
Tablet core: crospovidone, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide (anhydrous).
Film coating: macrogol 400, hypromellose, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

What does Levitra look like and what is in a package?

Levitra 5 mg film-coated tablets are orange with the Bayer cross on one side and the strength (5) on the other side. The tablets are supplied in a blister pack with 2, 4, 8, 12, or 20 tablets. Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Bayer AG
51368 Leverkusen
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Other sources of information

More information about this medicine is available on the European Medicines Agency website (<http://www.ema.europa.eu>).

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