

PACKAGE LEAFLET: INFORMATION FOR THE USER

VIAGRA 25 mg film-coated tablets
VIAGRA 50 mg film-coated tablets
VIAGRA 100 mg film-coated tablets
Sildenafil citrate

Read the entire package leaflet carefully before you start taking this medicine.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This package leaflet contains:

1. What is VIAGRA and what is it used for?
2. What do you need to know before taking VIAGRA?
3. How to take VIAGRA?
4. What are the possible side effects?
5. How to store VIAGRA?
6. Further information

1. WHAT IS VIAGRA AND WHAT IS IT USED FOR?

VIAGRA belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis when you are sexually excited. This allows blood to flow more easily into the penis. VIAGRA will only help you to get an erection if you are sexually stimulated. You should not take VIAGRA if you do not have erectile dysfunction. Women should not take VIAGRA.

VIAGRA is used to treat erectile dysfunction in men, which is sometimes referred to as impotence. This is when a man cannot get or keep a hard, erect penis suitable for sexual activity.

2. WHAT SHOULD YOU CONSIDER BEFORE TAKING VIAGRA?

VIAGRA must not be taken,

- if you are taking medicines called nitrates, as the combination can cause a potentially dangerous drop in your blood pressure. Talk to your doctor if you are taking any of these medicines, which are often prescribed for the relief of angina pectoris (or 'chest pain'). If you are unsure, ask your doctor or pharmacist.
- if you are taking medicines known as nitric oxide donors, such as amyl nitrite (also known as 'poppers'), as this combination can also cause a potentially dangerous drop in your blood pressure.

- if you are allergic (hypersensitive) to sildenafil or any of the other ingredients of VIAGRA.
- if you have a severe heart or liver problem.
- if you have recently had a stroke or a heart attack, or if you have low blood pressure.
- if you have certain rare inherited eye diseases (such as retinitis pigmentosa).
- if you have ever had a loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION).

Special care is required when taking VIAGRA

Talk to your doctor,

- if you have sickle cell anemia (a red blood cell disorder), leukemia (blood cancer), or multiple myeloma (bone marrow cancer). In these cases, special care may be needed when taking medicines to treat erectile dysfunction.
- if you have a deformation of your penis or Peyronie's disease.
- if you have heart problems. In this case, your doctor should carefully check whether your heart can handle the additional strain of sexual activity.
- if you currently have a gastrointestinal ulcer, or if there is a blood clotting disorder (such as hemophilia).
- if you notice a sudden decrease or loss of vision, stop taking VIAGRA and contact a doctor immediately.

You must not use VIAGRA simultaneously with other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

VIAGRA must not be taken by individuals under 18 years of age.

Special considerations for patients with kidney or liver diseases

You should inform your doctor if you have a kidney or liver dysfunction. Your doctor will decide if a lower dosage is necessary for you.

Taking VIAGRA with other medications

Please inform your doctor or pharmacist if you are taking or have recently taken any other medications, including non-prescription medications.

VIAGRA film-coated tablets and some medications can interact with each other, especially those used to treat heart pain. In a medical emergency, you should inform the medical personnel treating you that you have taken VIAGRA and when you took it. Do not take VIAGRA during treatment with other medications unless your doctor explicitly tells you that you can.

You must not take VIAGRA if you are taking medications called nitrates, as the combination of these medications can cause a potentially dangerous drop in your blood pressure. Talk to your doctor or pharmacist if you are taking any of these medications, which are often prescribed to relieve symptoms of angina pectoris (or 'heart pain').

You must not take VIAGRA if you are taking medications known as nitric oxide donors, such as amyl nitrite (also known as 'poppers'), as this combination can also cause a potentially dangerous drop in your blood pressure.

If you are taking medications known as protease inhibitors, used for the treatment of HIV infection, your doctor may start treatment with the lowest dose of VIAGRA (25 mg).

In some patients taking alpha-blockers for the treatment of high blood pressure or enlarged prostate, dizziness and lightheadedness may occur, which can be caused by low blood pressure when sitting or standing up quickly. Some patients experienced these symptoms when using VIAGRA together with alpha-blockers. This usually occurs within 4 hours after taking VIAGRA. To reduce the likelihood of these symptoms occurring, you should take your alpha-blocker in a regular daily dose before taking VIAGRA. In such a case, your doctor may prescribe a lower starting dose (25 mg) of VIAGRA.

Taking VIAGRA with food and drink

VIAGRA can be taken with or without food. However, you may find that it takes longer for VIAGRA to work if you take it with a heavy meal.

Alcohol consumption can temporarily impair the ability to achieve an erection. To get the best benefit from your medication, you should not drink excessive amounts of alcohol before taking VIAGRA.

Pregnancy and breastfeeding

VIAGRA is not intended for use by women.

Driving and using machines

VIAGRA can cause dizziness and affect vision. Be aware of how you react to VIAGRA before driving or operating machinery.

Important information about certain other ingredients of VIAGRA

Please only take VIAGRA after consulting your doctor if you know you have an intolerance to certain sugars, such as lactose.

3. HOW TO TAKE VIAGRA

Always take VIAGRA exactly as your doctor has instructed. Please consult your doctor or pharmacist if you are unsure. Unless otherwise prescribed by your doctor, the usual starting dose is 50 mg.

Do not take VIAGRA more than once a day.

You should take VIAGRA about one hour before intended sexual activity. Swallow the tablet whole with a glass of water.

Please talk to your doctor or pharmacist if you feel that the effect of VIAGRA is too strong or too weak.

VIAGRA will only help you achieve an erection if you are sexually stimulated. The time it takes for VIAGRA to work varies from patient to patient, but it usually takes between half an hour to an hour. You may find that VIAGRA takes longer to work if taken with a heavy meal.

You should inform your doctor if VIAGRA does not help you achieve an erection or if the erection does not last long enough to complete sexual intercourse.

If you have taken more VIAGRA than you should
Side effects may occur more frequently and be more severe. Doses above 100 mg do not increase effectiveness.

Do not take a higher dose than what your doctor has prescribed.

If you have taken more tablets than prescribed by your doctor, notify your doctor.

If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, VIAGRA can have side effects, although not everybody gets them. The side effects associated with Viagra are usually mild to moderate and of short duration.

If you experience chest pain during or after sexual intercourse:

- Adopt a semi-sitting position and try to relax.
- Do not use nitrates to treat your chest pain.
- Notify your doctor immediately.

All medicines, including VIAGRA, can cause allergic reactions. Contact your doctor immediately if you notice any of the following symptoms after taking VIAGRA: sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips, or throat.

Prolonged and sometimes painful erections have been reported after taking VIAGRA. If you have such an erection lasting more than 4 hours, you should seek medical advice immediately.

If you experience a sudden decrease or loss of vision, stop taking VIAGRA and contact your doctor immediately.

A very common side effect (may affect 1 in 10 patients) is headache.

Common side effects (may affect 1 to 10 in 100 patients) are: facial flushing, indigestion, visual disturbances (including color vision disturbances, light sensitivity, blurred vision, or reduced visual acuity), nasal congestion, and dizziness.

Occasional side effects (may affect 1 to 10 in 1,000 patients) are: vomiting, skin rashes, bleeding at the back of the eye, eye irritation, bloodshot/red eyes, eye pain, double vision, abnormal sensation in the eye, irregular heartbeat or palpitations, muscle pain, drowsiness, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain, and fatigue.

Rare side effects (may affect 1 to 10 in 10,000 patients) are: high blood pressure, low blood pressure, fainting, strokes, nosebleeds, and sudden hearing loss or deafness.

Other side effects reported from post-marketing experience include: palpitations, chest pain, sudden death, heart attacks, or temporary decreased blood flow to parts of the brain. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events are directly related to VIAGRA use. Cases of convulsions or seizures, as well as serious skin reactions with rash, blistering, peeling, and pain requiring immediate medical attention, have also been reported.

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

5. HOW TO STORE VIAGRA?

Keep medicines out of the reach of children.
Do not store above 30 °C.
Store in the original package to protect from moisture.

Do not use the medicine after the expiry date stated on the carton. The expiry date refers to the last day of the month.

Do not dispose of the medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures help protect the environment.

6. FURTHER INFORMATION

What VIAGRA contains

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg, or 100 mg of sildenafil (as citrate).
- The other ingredients are:
Tablet core: Microcrystalline cellulose, calcium hydrogen phosphate, croscarmellose sodium, magnesium stearate
Film coating: Hypromellose, titanium dioxide (E171), lactose, triacetin, indigo carmine aluminum lake (E132)

What VIAGRA looks like and contents of the pack

VIAGRA film-coated tablets are blue, rounded, diamond-shaped tablets. They are marked on one side with "PFIZER" and on the other with "VGR 25", "VGR 50" or "VGR 100". The tablets

are available in blister packs of 2, 4, 8, or 12 tablets (25 mg, 50 mg, or 100 mg) or as blister cards (50 mg). Not all pack sizes may be marketed in your country.

Marketing Authorization Holder and Manufacturer

The marketing authorization holder of VIAGRA is Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom.

The manufacturer of VIAGRA is Pfizer PGM, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

If you want more information about the medicine, please contact the local representative of the Marketing Authorization Holder.

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Detailed information on VIAGRA is available on the European Medicines Agency website
<http://www.ema.europa.eu> available.