

VIAGRA[®]

25 mg, 50 mg or 100 mg *film-coated tablets*

Sildenafil citrate

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What VIAGRA is and what it is used for
2. Before you take VIAGRA
3. How to take VIAGRA
4. Possible side effects
5. How to store VIAGRA
6. Further information

1. WHAT VIAGRA IS AND WHAT IT IS USED FOR

VIAGRA belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. 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. You should not take VIAGRA if you are a woman.

VIAGRA is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. BEFORE YOU TAKE VIAGRA

Do not take VIAGRA

- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
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- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a potentially dangerous decrease 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 loss of vision because of non-arteritic anterior ischaemic optic neuropathy (NAION)

Take special care with VIAGRA

Tell your doctor

- if you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow)
- If you have a deformity of your penis or Peyronie's Disease.
- if you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- if you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- if you experience sudden decrease or loss of vision, stop taking VIAGRA and contact your doctor immediately.

You should not use VIAGRA with any other oral or local treatments for erectile dysfunction.

Special considerations for children and adolescents

VIAGRA should not be given to individuals under the age of 18.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription.

VIAGRA tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any healthcare professional treating your condition that you have taken VIAGRA and when you did. Do not take VIAGRA with other medicines unless your doctor tells you that you can.

You should not take VIAGRA if you are taking medicines called nitrates as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take Viagra if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of VIAGRA.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness which may be caused by 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 occur within 4 hours after taking VIAGRA. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start VIAGRA. Your doctor may start you on a lower dose (25 mg) of VIAGRA.

Taking VIAGRA with food and drink

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

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking VIAGRA.

Pregnancy and Breast-feeding

VIAGRA is not indicated for use by women

Driving and using machines

VIAGRA can cause dizziness and can affect vision. You should be aware of how you react to VIAGRA before you drive or use machinery.

Important information about some of the ingredients of VIAGRA

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking VIAGRA.

3. HOW TO TAKE VIAGRA

Always take VIAGRA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is 50 mg.

You should not take VIAGRA more than once a day.

You should take VIAGRA about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you have the impression that the effect of VIAGRA is too strong or too weak, talk to your doctor or pharmacist.

VIAGRA will only help you to get an erection if you are sexually stimulated. The amount of time VIAGRA takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that VIAGRA takes longer to work if you take it with a heavy meal.

If VIAGRA does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

You should not use VIAGRA more than once a day.

If you take more VIAGRA than you should:

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, VIAGRA can cause side effects although not everybody gets them. The side effects reported in association with the use of VIAGRA are usually mild to moderate and of a short duration.

If you have chest pains during or after intercourse:

- Get in a semi-sitting position and try to relax
- **Do not use nitrates** to treat your chest pain
- Contact your doctor immediately

All medicines including VIAGRA can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking VIAGRA: sudden wheeziness, difficulty in 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 an erection which lasts for more than 4 hours, you should contact a doctor immediately.

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

A very common side effect (likely to occur in more than 1 in 10 patients) is headache.

Common side effects (likely to occur in 1 to 10 patients in 100): facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

Uncommon side effects (likely to occur in 1 to 10 patients in 1000) include: vomiting, skin rash, bleeding at the back of the eye, bloodshot eyes/red eyes, eye pain, double vision, abnormal sensation in the eye, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, chest pain and feeling tired.

Rare side effects (likely to occur in 1 to 10 patients in 10000) include: high blood pressure, low blood pressure, fainting, stroke, nosebleed and sudden decrease or loss of hearing.

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death, heart attack 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 were directly related to VIAGRA. Cases of convulsions or seizures have also been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

5. HOW TO STORE VIAGRA

Keep out of the reach and sight of children.

Do not store above 30 °C.

Store in the original package, in order to protect from moisture.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What VIAGRA contains

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

What VIAGRA looks like and contents of the pack

VIAGRA film-coated tablets are blue, with a rounded-diamond shape. They are marked "PFIZER" on one side and "VGR 25, "VGR 50" or "VGR 100" on the other side. The tablets are provided in blister packs containing 2, 4, 8 or 12 tablets. Some pack sizes may not be marketed in your country.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation 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.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last approved in 29 January 2009

Detailed information on VIAGRA is available on the European Medicines Agency (EMA) web site:
<http://www.ema.eu.int/>