

PACKAGE LEAFLET: INFORMATION FOR THE USER

VIAGRA

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

SILDENAFIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this 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 • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What VIAGRA is and what it is used for
2. What you need to know before you take VIAGRA
3. How to take VIAGRA
4. Possible side effects
5. How to store VIAGRA
6. Contents of the pack and other information

1. WHAT VIAGRA IS AND WHAT IT IS USED FOR

VIAGRA contains the active substance sildenafil which 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.

VIAGRA is a treatment for adult 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VIAGRA

Do not take VIAGRA

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall 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.

- If you are using any of the medicines known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a dangerous fall in your blood pressure.
- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Viagra have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- 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 due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking VIAGRA

- 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 carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (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.

You should not use VIAGRA with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take VIAGRA if you do not have erectile dysfunction.

You should not take VIAGRA if you are a woman.

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.

Children and adolescents

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

Other medicines and VIAGRA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

VIAGRA tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse 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 medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse 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 medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a dangerous fall in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat.

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 happen within 4 hours after taking VIAGRA. In order to reduce the chance that these symptoms might happen, 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.

VIAGRA with food and drink and alcohol

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, breast-feeding and fertility

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.

VIAGRA contains lactose

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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is 50 mg.

You should not take VIAGRA more than once a day.

Do not take VIAGRA film-coated tablets in combination with VIAGRA orodispersible tablets.

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

If you feel 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.

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, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 experience any of the following serious side effects stop taking VIAGRA and seek medical help immediately:

- An allergic reaction -this occurs uncommonly (may affect up to 1 in 100 people)
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains- this occurs uncommonly
If this occurs during or after intercourse
-Get in a semi-sitting position and try to relax.
-Do not use nitrates to treat your chest pain.
- Prolonged and sometimes painful erections – this occurs rarely (may affect up to 1 in 1,000 people). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision- this occurs rarely
- Serious skin reactions- this occurs rarely
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits- this occurs rarely

Other side effects:

Very common (may affect more than 1 in 10 people): headache.

Common (may affect up to 1 in 10 people): nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual

disturbance, stuffy nose and dizziness.

Uncommon (may affect up to 1 in 100 people): vomiting, skin rash, eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), , presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

Rare (may affect up to 1 in 1,000 people): fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note most but not all, 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 VIAGRA.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta

www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE VIAGRA

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What VIAGRA contains

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg or 100 mg 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 monohydrate, 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, 12 or 24 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 Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

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

Ireland

Pfizer Healthcare Ireland
Tel: 1800 633 363 (toll free)
Tel: +44 (0)1304 616161

Malta

V.J. Salomone Pharma Ltd.
Tel: + 356 21 22 01 74

United Kingdom

Pfizer Limited
Tel: +44 (0)1304 616161

This leaflet was last revised in 10/2015

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>