

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

VIAGRA® 25 mg Tablets

VIAGRA® 50 mg Tablets

VIAGRA® 100 mg Tablets

Read all of this leaflet carefully before you start taking VIAGRA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VIAGRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT VIAGRA CONTAINS:

The active substance of VIAGRA is sildenafil. Each tablet contains 25 mg, 50 mg, or 100 mg of sildenafil.

The other ingredients that make up the tablet are microcrystalline cellulose, calcium hydrogen, phosphate (anhydrous), croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, lactose, triacetin, indigo carmine aluminium lake.

2. WHAT VIAGRA IS USED FOR:

VIAGRA belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

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

VIAGRA works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.

VIAGRA will work only if you are sexually excited.

VIAGRA will not increase your sex drive.

VIAGRA is not for use in women.

VIAGRA is available only with a prescription.

3. BEFORE YOU TAKE VIAGRA:

Do not take VIAGRA:

- If you are allergic to sildenafil or any of the other ingredients of VIAGRA
- If you are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates
- If you have a severe liver or kidney problem
- If you are using cimetidine (used to treat ulcers), ketoconazole or itraconazole (used to treat fungal infections), erythromycin or rifampicin (used to treat infections) or ritonavir or saquinavir (used to treat HIV infections)

Take special care with VIAGRA:

Please tell your doctor:

- 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 have recently had a stroke or a heart attack, or if you have very low or very high blood pressure
- If you smoke
- If you are diabetic or have high cholesterol
- If you are taking a medication known as alpha blockers for hypertension or prostate problems
- If you have certain rare inherited eye diseases (such as retinitis pigmentosa)
- If you have an eye condition known as “crowded disc”
- If you have a hearing problem
- If you have any disease or deformity of your penis
- If you have any leukaemia (cancer of the blood cells), multiple myeloma (cancer of the bone marrow) or a disease of the blood called sickle cell anaemia
- If you have any bleeding disorder such as haemophilia or a stomach ulcer

- If you have previously had sudden loss of eyesight in one or more eyes

Pregnancy and breastfeeding:

VIAGRA is not indicated for use in women.

Driving and using machinery:

VIAGRA may produce dizziness and effects on vision. You should be aware of how you react to VIAGRA before you drive, operate hazardous machinery or perform hazardous tasks.

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.

Taking other medicines with VIAGRA:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VIAGRA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

Some medicines and VIAGRA may interact with each other. These include medicines called alpha-blockers (used to treat high blood pressure or prostate problems).

4. HOW TO TAKE VIAGRA:

Always take VIAGRA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 50 mg, taken about one hour before sexual activity. This dose may be increased to 100 mg or decreased to 25 mg by your doctor. Swallow the tablet whole with some 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.

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

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:

Taking a dose higher than 100 mg does not increase the effect of VIAGRA. However, it will result in an increase in undesirable effects and their severity.

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available seek help your nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS:

VIAGRA can have side effects.

Prolonged and painful erections have been reported after taking VIAGRA. If you have such an erection which lasts continuously for more than 4 hours, you should contact a doctor immediately.

Side effects reported include:

Nervous system disorders:

Headache, dizziness, tingling, sleepiness, loss of muscle coordination or muscle weakness, disturbance to nervous system, motion sickness, migraine, tremor, decrease reflexes, pain along the course of the nerves.

Vascular disorders:

Facial flushing, low blood pressure, nose bleed, shock, sudden dizziness on standing.

Gastrointestinal disorders:

Indigestion, dry mouth, diarrhoea, nausea, vomiting, inflammation of the stomach and intestines, stomach ache, inflammation of the gums, bleeding of the rectum, inflammation of the tongue, food pipe, colon or mouth, difficulty in swallowing.

Respiratory, thoracic and mediastinal disorders:

Stuffy nose, breathing problems, increased cough, increased phlegm.

Cardiac disorders:

Pounding heartbeat, severe pain in chest, impairment in conduction between chambers, heart failure, heart disease.

Eye disorders:

Effects on vision (including colour tinge to vision, increased brightness of light or blurred vision), inflammation of membrane of the eye, sensitivity to light, dry eyes, eye pain, cloudiness, bleeding in the eye, double vision, burning of the eye, swelling of the eye, pressure in the eye, detachment of the liquid in the eye from the inner lining of the eye.

Ear and labyrinth disorders:

ringing in the ears, deafness, ear pain.

Infections and infestations:

Flu-like symptoms, breathing tract infection, urinary tract infection, infection of the throat, infection of the voice box, fluid-filled sores on mouth or genitals.

Blood and lymphatic system disorders:

Decreased red blood cells, decreased white blood cells.

Metabolic and nutrition disorders:

Blood sugar levels that swing quickly from high to low, too much sugar in the blood, too much sodium in the blood, increased levels of uric acid in the blood, low blood sugar.

Psychiatric disorders:

Inability to sleep, depression, abnormal dreams.

Reproductive system and breast disorders:

Difficulty in achieving orgasm, abnormal ejaculation, prostate (a gland in males situated near the bladder) disorders, breast enlargement, genital swelling.

Musculoskeletal and connective tissue disorders:

Reduced ability of muscles to stretch, severe joint pain, muscle pain, back pain, inflammation around joints and tendons, inflammation of joints, tendon rupture, joint disease, bone pain.

Skin and subcutaneous tissue disorders:

Sweating, rash, skin ulcer, itching, swelling of the face, skin reactions.

Renal and urinary disorders:

Inflammation of the bladder, excessive urination at night, urinary frequency, loss of bladder control, blood in urine.

General disorders and administration site conditions:

Lack of energy, pain, chest pain, thirst, chills, swelling, swelling of the hands and feet.

Investigations:

Abnormal heart or liver function tests.

Injury, poisoning and procedural complications:

Accidental injury/fall.

Since its introduction on the market, the following events have been reported in men taking VIAGRA: red or bloodshot eyes, low blood pressure, allergic reactions, skin rash, seizures, fainting, stroke, high blood pressure, heart attack, sudden death, irregular heartbeat or temporary decreased blood flow to parts of the eye causing some loss of vision or irreversible blindness.

A sudden decrease or loss of hearing in one or both ears, with or without ringing in the ears and dizziness has been reported. You should contact your doctor as soon as you become aware of the hearing loss.

Not all side effects reported for VIAGRA are included in this leaflet. Should your general health worsen while taking VIAGRA, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF VIAGRA:

Store at or below 30 °C.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist who will dispose of them correctly.

7. PRESENTATION OF VIAGRA:

Blister strips in cartons of 1, 2, 4, 8 and 12.

8. IDENTIFICATION OF VIAGRA:

VIAGRA Tablets are available in three strengths:

- VIAGRA 25 mg: Blue, rounded diamond-shaped tablets, marked VGR 25 on one side and PFIZER on the other side

- VIAGRA 50 mg: Blue, rounded diamond-shaped tablets, marked VGR 50 on one side and PFIZER on the other side
- VIAGRA 100 mg: Blue, rounded diamond-shaped tablets, marked VGR 100 on one side and PFIZER on the other side

9. REGISTRATION NUMBERS:

VIAGRA 25 mg: 32/7.1.5/0621

VIAGRA 50 mg: 32/7.1.5/0622

VIAGRA 100 mg: 32/7.1.5/0623

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton, 2196

South Africa

11. DATE OF PUBLICATION:

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