PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VIAGRA® 25 mg film-coated tablets

VIAGRA® 50 mg film-coated tablets

VIAGRA® 100 mg film-coated tablets

Sildenafil citrate

Contains sugar: lactose monohydrate

Each VIAGRA 25 mg film-coated tablet contains 0,919 mg lactose monohydrate.

Each VIAGRA 50 mg film-coated tablet contains 1,837 mg lactose monohydrate.

Each VIAGRA 100 mg film-coated tablet contains 3,675 mg lactose monohydrate.

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, pharmacist, nurse or other health care provider.
- 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.

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

2. What VIAGRA is and what it 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.

3. What you need to know before you take VIAGRA

Do not take VIAGRA

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of VIAGRA (listed in section 6).
- If you are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates.
- If you have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION), a medical condition involving loss of vision due to damage to the optic nerve from insufficient blood supply.
- If you are using ketoconazole or itraconazole (used to treat fungal infections), erythromycin, ritonavir or saquinavir (used to treat HIV infections) or riociguat (used to treat pulmonary hypertension).
- If you have a severe liver or kidney problem.

Warnings and precautions

Take special care with VIAGRA:

VIAGRA offers no protection against sexually transmitted diseases. You should use protection measures necessary to guard against sexually transmitted diseases, including the human immunodeficiency virus (HIV/AIDS).

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 previously been advised against sexual activity.

- A large-scale study found evidence of an increased risk of retinal detachment with regular use of PDE5 inhibitors like VIAGRA. If you experience symptoms of retinal detachment (flashes of light, black spots, a curtain-like shadow in your vision or a limited field of vision), see an ophthalmologist immediately.
- If you have previously had sudden loss of eyesight in one or both eyes.
- If you have an eye condition known as “crowded disc”.
- If you are over 50 years of age.
- If you have diabetes or have high cholesterol.
- If you smoke.
- If you are taking a medication known as alpha blockers for hypertension (high blood pressure) or prostate problems.
- If you have recently had a stroke or a heart attack, or if you have very low or very high blood pressure.
- If you have certain rare inherited eye diseases (such as retinitis pigmentosa).
- If you have any bleeding disorder such as haemophilia or a stomach ulcer.
- 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 are taking other medicines for erection problems.
- If you have a hearing problem.

Other medicines and VIAGRA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

- You should not take VIAGRA if you are taking medicines called nitrates as the combination of these medicines 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 treatment of angina pectoris or “chest pain”.
- You should not take VIAGRA with cimetidine (medicine used to treat stomach ulcers) or erythromycin (an antibiotic) as they increase the blood levels of VIAGRA.
- You should not take VIAGRA with bosentan (used to treat high blood pressure in the pulmonary

artery), bosentan reduces the blood levels of VIAGRA.

- You should not take VIAGRA with rifampicin (used in treatment of tuberculosis), rifampicin may reduce the blood levels of VIAGRA.
- You should not take VIAGRA if you are taking medicines known as protease inhibitors, such as for the treatment of HIV, as they may interact with VIAGRA.
- Some medicines and VIAGRA may interact with each other. These include medicines called alpha-blockers (used to treat high blood pressure or prostate problems).
- Tell your doctor or pharmacist if you are taking medicines containing sacubitril/valsartan, used to treat heart failure.

Please consult your doctor, pharmacist or other health care provider for advice.

VIAGRA with food and drink

When VIAGRA is taken with a high fat meal, it may take a little longer to work.

Pregnancy and breastfeeding

VIAGRA is not indicated for use in women.

Driving and using machines

VIAGRA may cause dizziness and effect your vision. You should therefore be aware of how you react to VIAGRA before you drive, operate hazardous machinery or perform hazardous tasks.

It is not always possible to predict to what extent VIAGRA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VIAGRA affects them.

VIAGRA contains lactose

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

3. How to take VIAGRA

Do not share medicines prescribed for you with any other person.

Always take VIAGRA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 film-coated 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 high fat containing 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

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

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.

4. Possible side effects

VIAGRA can have side effects.

Not all side effects reported for VIAGRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VIAGRA, please consult your health care provider for advice.

If any of the following happens, stop taking VIAGRA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you experience a prolonged and painful erection which lasts continuously for more than 4 hours.
- If you experience chest pains at the start of or during sexual intercourse.
- If you experience sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- If you experience a sudden decrease or loss of vision.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VIAGRA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Facial flushing.
- Hot flushes.
- Stuffy nose.
- Runny nose.
- Flu-like symptoms.
- Dizziness.
- Effects on vision (including colour tinge to vision, blurred vision).
- Pounding heartbeat (palpitations).
- Nausea.
- Indigestion.

Less frequent side effects:

- Respiratory tract infection.
- Infection.
- Fluid-filled sores on mouth or genitals.
- Infection of the throat.
- Urinary tract infection.
- Infection of the voice box.
- Sinusitis.
- Decreased red blood cells.
- Decreased white blood cells.
- Blood sugar levels that swing quickly from high to low.
- Too much sugar in the blood.
- Too much salt in the blood.
- Gout (swelling of joint usually of the big toe accompanied by severe pain and heat).

- Increased levels of uric acid in the blood.
- Low blood sugar.
- Inability to sleep.
- Depression.
- Abnormal dreams.
- Difficulty in achieving orgasm.
- Sleepiness.
- Disturbance to nervous system.
- Tingling.
- Numbness.
- Loss of muscle coordination or muscle weakness.
- Pain along the course of the nerves.
- Fainting.
- Motion sickness.
- Migraines.
- Tremor.
- Decreased reflexes.
- Eye pain.
- Sensitivity to light.
- Increased brightness of light.
- Appearance of light flashes.
- Inflammation of membrane of the eye.
- Swelling of the eye.
- Eye strain.
- Dry eyes.
- Double vision.
- Yellow or red tinge in vision.
- Abnormal sensation in the eye.
- Burning of the eye.

- Eye irritation.
- Cloudiness of vision.
- Ringing in the ears.
- Deafness.
- Ear pain.
- Increased heart rate.
- Severe pain in chest.
- Impairment in conduction between chambers.
- Heart failure.
- Heart disease.
- Low blood pressure.
- Shock.
- Sudden dizziness on standing.
- Nosebleed.
- Dry or swollen nasal passage.
- Increased cough.
- Increased phlegm.
- Gastric reflux.
- Vomiting.
- Stomach-ache.
- Dry mouth.
- Diarrhoea.
- Inflammation of the stomach and intestines.
- Inflammation of the gums.
- Bleeding of the rectum.
- Reduced sensitivity in the mouth.
- Inflammation of the tongue, food pipe, colon or mouth.
- Sweating.
- Skin ulcer.

- Skin reactions.
- Shedding of the skin.
- Skin sensitivity to light.
- Redness of skin.
- Muscle pain.
- Severe joint pain.
- Back pain.
- Inflammation around joints and tendons.
- Inflammation of joints.
- Tendon rupture.
- Joint disease.
- Bone pain.
- Inflammation of the bladder.
- Excessive urination at night.
- Urinary frequency.
- Loss of bladder control.
- Blood in urine.
- Increased erection.
- Abnormal ejaculation.
- Prostate (a gland in males situated near the bladder) disorders.
- Breast enlargement.
- Genital swelling.
- Feeling hot.
- Lack of energy and strength.
- Pain.
- Thirst.
- Chest pain.
- Irritability.
- Chills.

- Swelling.
- Swelling of the hands and feet.
- Increased heart rate.
- Abnormal heart or liver function tests.
- Accidental injury/fall.

Other side effects:

- Fits, fits recurrence.
- Prolonged erection.
- Bleeding in the eye.
- Pressure in the eye.
- Detachment of the liquid in the eye from the inner lining of the eye.
- Damage of the **o**ptic nerve associated with loss of vision or blindness.
- Bloodshot eyes.
- Temporary loss of vision.
- Heart attack.
- High blood pressure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VIAGRA.

5. How to store VIAGRA

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store the blisters in the carton until required for use
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

- Do not store in a bathroom.
- Do not use after the expiry date stated on the blister or carton.

6. Contents of the pack and other information

What VIAGRA contains

- The active substance of VIAGRA is sildenafil. Each film-coated tablet contains 25 mg, 50 mg, or 100 mg of sildenafil.
- The other ingredients are calcium hydrogen phosphate (anhydrous), croscarmellose sodium, hypromellose, indigo carmine aluminium lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, triacetin.

What VIAGRA looks like and contents of the pack

VIAGRA film-coated tablets are available in three strengths:

VIAGRA 25 mg: Blue, rounded diamond shaped film-coated tablets, debossed with “VGR 25” on one side and “VIAGRA” on the other.

VIAGRA 50 mg: Blue, rounded diamond shaped film-coated tablets, debossed with “VGR 50” on one side and “VIAGRA” on the other.

VIAGRA 100 mg: Blue, rounded diamond shaped film-coated tablets, debossed with “VGR 100” on one side and “VIAGRA” on the other.

VIAGRA 25 mg, 50 mg, 100 mg: Aluminium foil/clear PVC blisters are packed into a white printed outer cardboard carton with a package insert. The film-coated tablets are available in pack sizes of 1, 2, 4, 8 and 12.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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BOTSWANA: S3

VIAGRA 25 mg: Reg. No.: BOT9900339

VIAGRA 50 mg: Reg. No.: BOT9900340

VIAGRA 100 mg: Reg. No.: BOT9900341

NAMIBIA: NS2

VIAGRA 25 mg: Reg. No.: 2001/A7.1/005

VIAGRA 50 mg: Reg. No.: 2001/A7.1/003

VIAGRA 100 mg: Reg. No.: 2001/A7.1/004

ZAMBIA: POM

VIAGRA 50 mg – Reg. No.: 120/003

ZIMBABWE: PP

VIAGRA 25 mg: Reg. No.: 2021/31/6145

VIAGRA 50 mg: Reg. No.: 2000/21.8/3778

VIAGRA 100 mg: Reg. No.: 2000/21.8/3779