

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RAVIAG 25 Film-coated tablets

RAVIAG 50 Film-coated tablets

RAVIAG 100 Film-coated tablets

Sildenafil citrate

Sugar free

Read all of this leaflet carefully before you start taking RAVIAG

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

1. What RAVIAG is and what it is used for

- RAVIAG contain sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It 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.

- RAVIAG is used to treat erectile dysfunction, more known as impotence, in men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.
- RAVIAG will work only if you are sexually excited.
- RAVIAG will not increase your sex drive.
- RAVIAG is not for use in women.
- RAVIAG is not indicated for use by children.

2. What you need to know before you take RAVIAG

Do not take RAVIAG:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of RAVIAG (listed in section 6).
- If you are taking medicines called nitrates and nitric oxide donors, 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.
- 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).
- If you have a severe heart, kidney or liver problems.

If you think any of these apply to you, do not take RAVIAG, talk to your doctor and follow the advice given.

Warnings and precautions

Take special care with RAVIAG:

- 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 any other problem with your penis.
- If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- If you have problems with your heart. Your doctor will determine if your heart is healthy enough to handle the extra strain of having sex.

- If you have recently had a stroke or a heart attack, or if you have any disorder of your heart rate or rhythm (such as beating too fast, too slow, or irregularly).
- 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 ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).
- If you are taking any other oral or local treatments for erectile dysfunction.
- If you have stomach ulcers or any types of bleeding problems.
- If you are over 65 years.
- If you have a sudden hearing problem in one or both ears

Other medicines and RAVIAG

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

Remember to tell your doctor about your treatment with RAVIAG tablets if you are prescribed another medicine while the treatment is still ongoing. This is especially important, if you are taking any medicines: RAVIAG 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 RAVIAG tablets and when you did. Do not take RAVIAG tablets with other medicines unless your doctor tells you that you can.

Especially tell your doctor if you are taking:

- Medicines called nitrates (used for relief of angina pectoris/ 'chest pain'), as the combination of these medicines with RAVIAG may lead to a dangerous fall in your blood pressure.
- Medicines known as nitric oxide donors, such as amyl nitrate ('poppers'), as the combination with RAVIAG may also lead to a dangerous fall in your blood pressure.
- Cimetidine, a medicine used to treat ulcers.
- Some medicines used to treat fungal infections including ketoconazole and itraconazole.
- Some antibiotics including erythromycin.
- Some medicines used to treat HIV such as saquinavir or ritonavir.

- Medicines called alpha-blockers (such as doxazosin, silodosin, prazosin, tamsulosin, alfuzosin and terazosin). These are used to treat high blood pressure or prostate problems. Some patients may experience dizziness and light-headedness (which may be caused by low blood pressure upon sitting or standing up quickly) when taking RAVIAG with alpha-blockers. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start RAVIAG. Your doctor may start you on a lower dose of RAVIAG.

RAVIAG with food, drink and alcohol

RAVIAG can be taken with or without food. However, you may find that RAVIAG 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 RAVIAG, you are advised not to drink excessive amounts of alcohol before taking RAVIAG.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

RAVIAG is not indicated for use by women.

Driving and using machines

It is not always possible to predict to what extent RAVIAG 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 RAVIAG affects them.

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

3. How to take RAVIAG

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

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

The usual starting dose is 50 mg, however based on your condition, a lower starting dose (i.e. 25 mg) may be recommended by your doctor.

RAVIAG is to be taken about one hour before you plan to have sex.

Based upon your response your doctor may increase your dose to 100 mg or decrease the dose to 25 mg.

The maximum daily dose is 100 mg.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Do not chew.

You should not take RAVIAG more than once a day.

Your doctor will tell you how long your treatment with RAVIAG will last. If you have the impression that the effect of RAVIAG is too strong or too weak, tell your doctor or pharmacist.

If RAVIAG 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 RAVIAG than you should

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

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.

Take along any tablets that are left, the container and the label so that the hospital will know what you have taken.

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

If you forget to take RAVIAG

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects

RAVIAG can have side effects.

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

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

- Sudden wheeziness, shortness of breath, difficulty in breathing, chest constriction, swelling of the eyelids, face, lips or throat, rashes, hives, itching, or high temperature.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Eye bleeding.
- Blood in urine.
- Shock.
- Heart attack.
- Chest pain.

These are all serious side effects. You may need urgent medical attention.

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.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, flushing, dizziness.
- Abnormal vision (predominantly colour tinge to vision, but also increased perception of light or blurred vision).
- Fast and irregular heartbeats.
- Nasal congestion.
- Indigestion.

Less frequent side effects or frequency unknown:

- Sensitivity to sunlight (photophobia).
- Double vision, temporary loss of vision/ decreased vision, cataract.
- Red eyes, burning eyes, abnormal sensation in the eye, dry eyes and eye pain.
- Painful erection (priapism).
- Night time urination, increased urination.
- Breast enlargement.
- Unable to hold urine, abnormal ejaculation, swelling of penis.
- Accidental injury.
- Inflammation which causes abdominal pain and diarrhoea.
- Difficulty in swallowing (dysphagia).
- Pain in upper abdomen that may become either worse or better with eating (gastritis).
- Rectal bleeding.
- Reduction in red blood cells which makes the skin pale and cause weakness and breathlessness, persistent sore throat and frequent infections.
- Low sugar levels in the blood (hypoglycaemia) presenting with sweating.
- Decreased motor function such as hand eye co-ordination (hypoglycaemic reaction).
- High levels of sodium in the blood manifested as loss of appetite, restlessness, nausea, and vomiting (hypernatraemia).
- Tendon rupture.
- Swelling and difficulty moving the particular joint where the inflammation occurs (tenosynovitis).
- Muscles becoming progressively weaker during periods of activity and improve after rest (myasthenia gravis).
- Lack of coordination of muscle movements.
- Spinning sensation.
- Depression.
- Asthma, shortness of breath.
- Inflammation of the air passages within the lungs manifested by cough (bronchitis).
- Shingles (herpes simplex), skin ulcer, scaling of skin (exfoliative dermatitis).
- High blood pressure, low blood pressure.

- Migraine.
- Fainting.
- Dizziness upon sudden standing up (postural hypotension).
- Feeling of weakness, pain, chills.
- Accidental fall.
- Inflammation or irritation of mucous lining of the tongue (glossitis) or swallowing tube leading to the stomach (oesophagitis) or cheeks, gums, tongue, lips, throat (stomatitis).
- Abdominal pain, loose motions, nausea and vomiting (being sick).
- Dry mouth, abnormal test results of the liver.
- Thirst.
- Swelling (oedema).
- Painful joints, joint swelling.
- Muscle pain, bone pain.
- Increased muscle tone.
- Severe nerve pain, weakness tingling and numbness (neuropathy).
- Tingling or numbness of the hands or feet (paraesthesia).
- Tremor.
- Insomnia, feeling sleepy, abnormal dreams.
- Reflexes decreased.
- Increased perception to pain.
- Inflammation of the larynx (voice box) causing hoarseness voice or the complete loss of the voice (laryngitis).
- Sore throat (pharyngitis).
- Sinusitis.
- Increased sputum, increased cough.
- Sweating.
- Localised rash or irritation of the skin (contact dermatitis).
- Ringing in the ears (tinnitus), deafness, ear pain.

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, 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 RAVIAG.

5. How to store RAVIAG

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package/ container.
- Keep the blisters in the outer carton.
- Protect from light / moisture.
- Do not store in a bathroom.
- Do not take use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RAVIAG contains

The active substance is sildenafil.

RAVIAG 25: Each film-coated tablet contains sildenafil citrate equivalent to sildenafil 25 mg.

RAVIAG 50: Each film-coated tablet contains sildenafil citrate equivalent to sildenafil 50 mg.

RAVIAG 100: Each film-coated tablet contains sildenafil citrate equivalent to sildenafil 100 mg.

The other ingredients are calcium hydrogen phosphate, cellulose microcrystalline, croscarmellose sodium and magnesium stearate in the tablet core. The film-coat contains aluminium lake, hypromellose, indigo carmine, iron oxide red, polyethylene glycol and titanium dioxide.

What RAVIAG looks like and contents of the pack

RAVIAG 25: Red coloured, rounded triangular shaped, film-coated tablets, with 'S21' engraved on one side and plain on the other side.

RAVIAG 50: Red coloured, rounded triangular shaped, film-coated tablets, with 'S22' engraved on one side and plain on the other side.

RAVIAG 100: Red coloured, rounded triangular shaped, film-coated tablets, with 'S23' engraved on one side and plain on the other side.

The RAVIAG tablets are packed in PVC/PE/PVdC blister pack (triplex blister pack), transparent PVC blister pack and cold form blister pack.

Transparent PVC blister pack:

Clear PVC film with hard tempered, heat-sealable aluminium foil coated with heat seal lacquer on the inner side of the foil – should be odourless.

PVC/PE/PVdC blister pack (triplex blister pack):

The pack comprises of clear transparent PVC film, laminated with polyethylene (PE) and coated with PVdC on the inner side, with a backing of hard tempered heat-sealable aluminium foil coated with heat seal lacquer.

Cold form blister pack:

It comprises of cold forming blister laminate of aluminium foil (one side bright, soft tempered, plain, dull side lacquered to oriented polyamide film; bright side lacquer laminated to PVC film) with a backing of hard tempered, heat sealable aluminium foil coated with heat seal lacquer and of printable quality.

Carton contains 4 tablets packed in blister pack. Each blister strip contains 4 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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