

1.3.2.1 Approved Patient Information Leaflet

SCHEDULING STATUS

S4

SILDENAFIL VIATRIS (film-coated tablets)

Sildenafil

Sugar free

Read all of this leaflet carefully before you start taking SILDENAFIL VIATRIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SILDENAFIL VIATRIS 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 SILDENAFIL VIATRIS is and what it is used for
2. What you need to know before you take SILDENAFIL VIATRIS
3. How to take SILDENAFIL VIATRIS
4. Possible side effects
5. How to store SILDENAFIL VIATRIS
6. Contents of the pack and other information

1. What SILDENAFIL VIATRIS is and what it is used for

1.3.2.1 Approved Patient Information Leaflet

What SILDENAFIL VIATRIS is:

SILDENAFIL VIATRIS contains the active ingredient sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

What SILDENAFIL VIATRIS is used for:

SILDENAFIL VIATRIS brings down blood pressure in the lungs by widening the blood vessels in the lungs.

SILDENAFIL VIATRIS is used to treat adults with high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension).

2. What you need to know before you take SILDENAFIL VIATRIS

Do not take SILDENAFIL VIATRIS:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of SILDENAFIL VIATRIS (listed in section 6).
- If you are taking medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of chest pain (or “angina pectoris”). SILDENAFIL VIATRIS can cause a serious increase in the effects of these medicines.
- If you are taking riociguat. Riociguat 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). Other medicines that work in a similar manner as SILDENAFIL VIATRIS to open veins and can reduce blood pressure even more when taken together with SILDENAFIL VIATRIS.
- If you have recently had a stroke or a heart attack.
- if you have severe liver or kidney disease.
- If you have very low blood pressure (<90/50 mmHg).

1.3.2.1 Approved Patient Information Leaflet

- If you are taking a medicine to treat fungal infections such as ketoconazole or itraconazole or medicines containing ritonavir or saquinavir (for HIV).
- If you are taking an antibiotic such as erythromycin to treat certain infections.
- If you have severe problems with your heart (such as unstable angina or heart failure).
- If you have ever had loss of vision because of a problem with blood flow to the nerve in the eye called non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

Take special care with SILDENAFIL VIATRIS:

- If you have a disease due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.
- If you have a severe heart problem.
- If you have a problem with the pumping chambers of your heart.
- If you have high blood pressure in the blood vessels in the lungs.
- If you have low blood pressure at rest.
- If you lose a large amount of body fluids (dehydration) which can occur when you sweat a lot or do not drink enough liquids. This can happen if you are sick with a fever, vomiting, or have diarrhoea.
- If you have a rare inherited eye disease (retinitis pigmentosa) or a certain rare eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION). NAION causes loss of blood flow to the optic nerve resulting in decreased or loss of vision.
- If you have an abnormality of red blood cells (sickle cell anaemia), cancer of blood cells (leukaemia), cancer of bone marrow (multiple myeloma), or any disease or deformity of the penis.
- If you currently have a stomach ulcer, a bleeding disorder (such as haemophilia) or problems

1.3.2.1 Approved Patient Information Leaflet

with nose bleeds.

- If you are taking a medicine called an alpha-blocker as this may lead to low blood pressure.
- If you are taking blood thinning medicines.
- If you take medicines for erectile dysfunction.
- If you have a condition due to a blocked or narrow vein in the lungs rather than a blocked or narrow artery.
- If you are taking a medicine called bosentan used to treat high blood pressure in the vessels that carry blood to lungs.
- If you have kidney or liver problems, as your dose may need to be adjusted.
- If you are taking SILDENAFIL VIATRIS with other medicines used for pulmonary arterial hypertension or erectile dysfunction.

A large-scale study found evidence of an increased risk of retinal detachment with regular use of PDE5 inhibitors like SILDENAFIL VIATRIS. 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.

Prolonged and sometimes painful erections have been reported in men after taking sildenafil. If you have an erection, which lasts continuously for more than 4 hours, stop taking SILDENAFIL VIATRIS and contact your doctor immediately (*see also section 4*).

Children and adolescents

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

Other medicines and SILDENAFIL VIATRIS

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

1.3.2.1 Approved Patient Information Leaflet

Especially tell your doctor if you are taking:

- Medicines containing nitrates, or nitric oxide donors such as amyl nitrate (“poppers”). These medicines are often given for relief of angina pectoris or “chest pain” (*see section 2. Before you take SILDENAFIL VIATRIS*).
- Tell your doctor or pharmacist if you are already taking riociguat for pulmonary hypertension.
- Therapies for pulmonary hypertension (e.g. bosentan, ilopros).
- Medicines containing St. John’s Wort (herbal medicine), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy).
- Medicine called cimetidine to treat conditions such as stomach ulcers or when the stomach produces too much acid.
- Grapefruit juice.
- Blood thinning medicines (for example warfarin) although these did not result in any side effects.
- Medicines containing erythromycin, clarithromycin, telithromycin (these are antibiotics used to treat certain bacterial infections), saquinavir or ritonavir (for HIV) or nefazodone (for mental depression), as your dose may need to be adjusted.
- Alpha-blocker therapy (e.g. doxazosin) for the treatment of high blood pressure or prostate problems, as the combination of the two medicines may cause symptoms resulting in the lowering of your blood pressure (e.g. dizziness, light headedness).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you take SILDENAFIL VIATRIS.

1.3.2.1 Approved Patient Information Leaflet

Pregnancy

Do not take SILDENAFIL VIATRIS if you are pregnant or plan to fall pregnant.

Before you take SILDENAFIL VIATRIS, ensure that you are using a reliable pregnancy preventing method (contraceptive).

Breastfeeding

You should not take SILDENAFIL VIATRIS if you are breastfeeding your child. SILDENAFIL VIATRIS passes into your breast milk at very low levels.

Driving and using machines

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

3. How to take SILDENAFIL VIATRIS

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

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

For adults the recommended dose is 20 mg three times a day 6 to 8 hours apart, taken with or without food.

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

If you take more SILDENAFIL VIATRIS than you should

1.3.2.1 Approved Patient Information Leaflet

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

If you forget to take SILDENAFIL VIATRIS

If you forget to take SILDENAFIL VIATRIS, take a dose as soon as you remember, then continue to take your medicine at the usual times. Do not take a double dose to make up for a forgotten dose.

If you stop taking SILDENAFIL VIATRIS

Suddenly stopping your treatment with SILDENAFIL VIATRIS may lead to your symptoms getting worse. Do not stop taking SILDENAFIL VIATRIS unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

4. Possible side effects

SILDENAFIL VIATRIS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

1.3.2.1 Approved Patient Information Leaflet

Tell your doctor if you notice any of the following:

Frequent

- headache, facial flushing, indigestion, diarrhoea and pain in the arms or legs;
- infection under the skin, flu-like symptoms, inflammation of the sinuses, reduced number of red blood cells (anaemia);
- fluid retention, “pins and needles”-like sensation, burning sensation, reduced sense of touch;
- difficulty sleeping, anxiety, migraine, shaking;
- bleeding at the back of the eye, effects on vision, blurred vision and light sensitivity, effects on colour vision, eye irritation, bloodshot eyes/red eyes, reduced sharpness of vision, double vision, abnormal sensation in the eye;
- bronchitis, cough, vertigo, nosebleed, runny nose, stuffy nose, inflammation on the inside of the nose (swelling, itching), stomach inflammation, gastroenteritis, heartburn, piles, abdominal distension, dry mouth;
- hair loss, redness of the skin, night sweats, muscle aches, back pain and increased body temperature, weight increase, breast enlargement in men.

Frequency unknown

- sudden decrease or loss of vision;
- sudden decrease or loss of hearing with or without tinnitus (noises in your ear) and/or dizziness;
- decreased blood pressure;
- loss of blood from damaged blood vessels;
- skin rash;
- prolonged (an erection, which lasts continuously for more than 4 hours) and sometimes

1.3.2.1 Approved Patient Information Leaflet

painful erections, penile bleeding, presence of blood in semen and/or urine.

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

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions 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 SILDENAFIL VIATRIS.

5. How to store SILDENAFIL VIATRIS

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the blisters in the carton until required for use.
- Do not use after the expiry date stated on the label/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 SILDENAFIL VIATRIS contains

1.3.2.1 Approved Patient Information Leaflet

- The active ingredient is sildenafil.

Each film-coated tablet contains sildenafil citrate equivalent to 100 mg sildenafil. Sugar free.

- The other ingredients are hypromellose, titanium dioxide (E171), FD & C blue # 2 /indigo carmine aluminium lake, triacetin, FD&C blue # 2/indigo carmine aluminium lake.

What SILDENAFIL VIATRIS looks like and contents of the pack

SILDENAFIL VIATRIS is a white, film-coated, round, biconvex tablet debossed with 'M' on one side of the tablet and 'SL over 20' on the other side.

SILDENAFIL VIATRIS tablets are packed in PVC Blister Pack (marketable pack) comprises of clear, transparent, non-toxic PVC on one side and hard tempered aluminium foil (coated with VMCH heat seal lacquer) on the other side.

Suitable number of blister strips will be placed in an outer cardboard carton.

Holder of Certificate of Registration

VIATRIS SOUTH AFRICA (PTY) LTD

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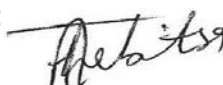
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Page 10 of 11

1.3.2.1 Approved Patient Information Leaflet

Access to the corresponding Professional Information

To be confirmed.

