

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SOLIRA 25 mg film-coated tablets

SOLIRA 50 mg film-coated tablets

SOLIRA 100 mg film-coated tablets

Sildenafil citrate

Contains sugar

SOLIRA 25: Each film-coated tablet contains 2,1 mg lactose monohydrate.

SOLIRA 50: Each film-coated tablet contains 4,2 mg lactose monohydrate.

SOLIRA 100: Each film-coated tablet contains 8,4 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking SOLIRA

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

1. What SOLIRA is and what it is used for

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

SOLIRA 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.

SOLIRA 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.

SOLIRA will work only if you are sexually excited.

SOLIRA will not increase your sex drive.

SOLIRA is not for use in women.

2. What you need to know before you take SOLIRA

Do not take SOLIRA:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of SOLIRA (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. 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). PDE5 inhibitors, such as SOLIRA have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- 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 severe problems with your heart (such as unstable angina or heart failure).
- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).
- If you have a severe kidney 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).

Warnings and precautions

Take special care with SOLIRA:

- 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 have a deformity of your penis or Peyronie's disease.
- 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 currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking SOLIRA and contact your doctor immediately.
- You should not use SOLIRA with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.
- You should not use SOLIRA with any other oral or local treatments for erectile dysfunction.
- You should not take SOLIRA if you do not have erectile dysfunction.

Children and adolescents

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

Other medicines and SOLIRA

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

SOLIRA 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 SOLIRA and when you did. Do not take SOLIRA with other medicines unless your doctor tells you that you can.

You should not take SOLIRA 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 SOLIRA 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 SOLIRA.

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 SOLIRA with alpha-blockers. This is most likely to happen within 4 hours after taking SOLIRA. 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 SOLIRA. Your doctor may start you on a lower dose (25 mg) of SOLIRA.

SOLIRA with food and drink

SOLIRA can be taken with or without food. However, you may find that SOLIRA 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 SOLIRA.

Pregnancy, breastfeeding and fertility

SOLIRA is not indicated for use in women.

Driving and using machines

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

SOLIRA contains lactose monohydrate

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

3. How to take SOLIRA

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

Always take SOLIRA 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 tablet whole with some water.

SOLIRA will only help you to get an erection if you are sexually stimulated. The amount of time

SOLIRA takes to work varies from person to person, but it normally takes between half an hour and one hour.

If SOLIRA 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 SOLIRA more than once a day.

If you have the impression that the effect of SOLIRA is too strong or too weak, tell your doctor or pharmacist.

If you take more SOLIRA than you should

Taking a dose higher than 100 mg does not increase the effect of SOLIRA. However, it will result in an increase in undesirable effects and their severity. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

SOLIRA can have side effects.

Not all side effects reported for SOLIRA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SOLIRA, please consult your health care provider for advice.

If any of the following happens, stop taking SOLIRA 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

SOLIRA. 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:

Less frequent

- chest pains,
- prolonged and sometimes painful erections,
- a sudden decrease or loss of vision,
- serious skin reactions (symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever),
- seizures or fits.

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

Tell your doctor if you notice any of the following:

Frequent

- headache, dizziness
- nausea, indigestion,
- facial flushing, hot flush,
- colour tinge to vision, blurred vision, visual disturbance, stuffy nose.

Less frequent

- 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, nosebleed,
- upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn),
- presence of blood in urine,
- pain in the arms or legs,
- feeling hot, feeling tired,
- 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,
- sudden decrease or loss of hearing.

Frequency unknown

- unstable angina (a heart condition),
- sudden death.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on

the safety of SOLIRA.

5. How to store SOLIRA

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton/blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLIRA contains

The active substance in SOLIRA is sildenafil citrate.

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

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

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

The other ingredients are calcium hydrogen phosphate, croscarmellose sodium, hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose (E460) and Opadry II Blue (containing FD&C Blue indigo carmine (colourant) (E132), hypromellose (E464), lactose monohydrate, titanium dioxide (E171), triacetin).

What SOLIRA looks like and contents of the pack

SOLIRA 25: Light blue to blue, oval shaped, biconvex film-coated tablets, plain on both sides.

SOLIRA 50: Light blue to blue, oval shaped, biconvex film-coated tablets, engraved 50 on one side and plain on other side.

SOLIRA 100: Light blue to blue, oval shaped, bevel, film-coated tablets, engraved 100 on one side and plain on other side.

Clear PVC/PVDC/Aluminium blister strips placed in an outer carton.

Aluminium/Aluminium blister strips placed in an outer carton.

Pack size: 2 or 4 tablets.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

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0157

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