PATIENT INFORMATION LEAFLET FOR SILREXIA 25 / 50 / 100

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

Silrexia 25 film coated tablets

Silrexia 50 film coated tablets

Silrexia 100 film coated tablets

Please read this leaflet carefully before taking Silrexia tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **Silrexia** 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 SILREXIA CONTAINS

Active ingredient:

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

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

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

Inactive ingredients:

Anhydrous calcium hydrogen phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose and Opadry White (containing hypromellose, lactose monohydrate, titanium dioxide and triacetin).

Contains sugar: lactose monohydrate.

2. WHAT SILREXIA IS USED FOR

SILREXIA is used for the treatment of erection problems in men.

SILREXIA IS NOT AN APHRODISIAC.

3. BEFORE YOU TAKE SILREXIA

Do not take Silrexia:

- If you are hypersensitive (allergic) to sildenafil or any of the other ingredients of **Silrexia** (see **WHAT SILREXIA CONTAINS**).
- If you have a heart, severe liver or kidney disorder.
- If you are taking medicine such as nitrates or nitric oxide donors for high blood pressure or heart problems (such as chest pain). Please inform your doctor.
- If you are taking medicines such as ritonavir, saquinavir, ketoconazole or itraconazole (see **Taking other medicines with Silrexia**).
- If you have ever had loss of vision due to an eye condition known as non-arteritic anterior ischaemic optic neuropathy (NAION).

Take special care with Silrexia:

- If you had a heart attack or stroke or other life-threatening heart problems within the last 6 months.
- If you have high or low blood pressure.
- If you have any heart disorders such as angina (chest pain).
- If you have eye disorders (such as retinitis pigmentosa, a disorder that affects the eye's ability to respond to light). Please consult your doctor before taking **Silrexia**.
- If you are an elderly patient. Follow the dose precisely as prescribed to you.
- If you have a stomach ulcer or a bleeding disorder.
- If you are taking other medications for erection problems or any other diseases. Please

consult your doctor or pharmacist before taking **Silrexia**.

- You should seek immediate medical assistance in the event of an erection that persists longer than 4 hours after taking **Silrexia**. Painful erections lasting longer than 6 hours (priapism) should be treated immediately, as damage to your penis and permanent loss of potency could result.
- **Silrexia** should be used with caution if you have an anatomical deformation of your penis. Please consult your doctor. Your doctor will examine you and determine the cause of your disorder before starting treatment with **Silrexia**.
- You should contact your doctor if you suffer any hearing loss while you are taking **Silrexia**.
- **Silrexia** offers no protection against sexually transmitted diseases. You should use protective measures necessary to guard against sexually transmitted diseases, including the human immunodeficiency virus (HIV/AIDS).
- You should take precautions to prevent unwanted pregnancy.

Taking Silrexia with food and drink:

Silrexia can be taken with or without food. However, you may find that **Silrexia** takes longer to start working if you take it with a fatty meal.

Pregnancy and breastfeeding:

Do not take **Silrexia** if you are female.

Driving and using machinery:

Silrexia can lead to dizziness and influence your vision. You should exercise caution before driving a vehicle, operating hazardous machinery or performing hazardous tasks.

Important information about some of the ingredients of Silrexia:

Silrexia contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars (you cannot digest some sugars), contact

your doctor before taking **Silrexia**.

Taking other medicines with Silrexia:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Medicines known to interact with **Silrexia** are:

- Ketoconazole or itraconazole (used to treat fungal infections).
- Cimetidine (used to treat ulcers).
- Erythromycin (used to treat bacterial infections).
- Saquinavir, ritonavir and other HIV medicines (used to treat HIV infection).
- Rifampicin (used to treat tuberculosis (TB)).
- Nitrates or nitric oxide donors (used to treat chest pain (angina)).
- Antihypertensive medication (used to treat high blood pressure).
- Doxazosin or alpha-blockers (used to treat high blood pressure or an enlarged prostate).

4. HOW TO USE SILREXIA

The dose of **Silrexia** will be different for different patients depending on the seriousness of your condition and the effectiveness and tolerability of **Silrexia**.

*Do not take more **Silrexia** than was prescribed to you or take **Silrexia** more frequently.*

Adults:

The recommended dose is one 50 mg tablet per day one hour before sexual intercourse. The maximum recommended dose is 100 mg. The recommended dosing frequency is once per day.

Elderly and patients with liver or kidney disorders:

Your doctor may recommend a lower starting dose of one 25 mg tablet per day, to be taken one hour before sexual intercourse.

If you take more Silrexia than you should:

In the event of overdosage, consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

5. POSSIBLE SIDE EFFECTS

Silrexia can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash, hives or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Silrexia**. 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:

- Yellowing of your skin and eyes, also called jaundice.
- Chest pain (angina).
- Changes in the way your heart beats (such as beating faster than normal or skipping beats).
- Heart attack (chest pain or tightness, pain in your arm or body, shortness of breath).
- Heart problems or abnormal readings on electrocardiogram (ECG) when tests are done.
- Seizures (fits).
- Migraine (severe debilitating headache, nausea, vomiting, impaired vision).

- Loss of vision due to an eye condition known as non-arteritic anterior ischaemic optic neuropathy (NAION).
- Bleeding, swelling or build-up of pressure around your eyes.
- Low blood pressure when you stand up (light-headedness or dizziness).
- Shortness of breath or difficulty breathing (asthma).
- Signs of recurrent infections such as fever or sore throat.
- Stroke (severe headache, muscle weakness on one side of your body, loss of coordination or balance, difficulty speaking or swallowing).
- Cellulitis (bacterial skin infection causing rapid swelling, pain, redness and tenderness in the area affected).
- Urinating frequently or leaking urine involuntary.
- Blood in your urine.
- Bladder infection (pain and burning while passing urine, frequent small amounts of urine).
- Prolonged or painful erection.
- Unstable diabetes (uncontrolled sugar levels in your body).
- Sudden drop in your blood sugar (confusion, disorientation or dizziness).
- Bleeding of your rectum (presence of blood when you pass stools, pain or discomfort).

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects occur more frequently:

- Difficulty sleeping.
- Feeling anxious.
- Headache or dizziness.
- Problems with seeing colours.
- Eye irritation, pain or redness.
- Sensitivity of your eyes to bright light.
- Vertigo (spinning feeling).
- Nose bleeds.
- Nasal congestion.
- Indigestion (heartburn), diarrhoea, nausea or vomiting.
- Flushing or redness of your skin.

The following side effects occur less frequently:

- Anaemia (unusual weakness, tiredness and pallor of your skin).
- Thirst.
- Gout or high levels of uric acid in your blood (painful, swollen and stiff joints).
- High blood sugar levels (increased thirst, frequent urination).
- High levels of sodium in your blood (tiredness, weakness, irritability).
- Feeling depressed.
- Abnormal dreams.
- Inability to get an orgasm during sexual intercourse.
- Lack of coordination or muscle control.
- Muscle spasms.
- Pain or burning feeling along your nerves, nerve damage (weakness, numbness or pain).
- Paraesthesia (burning or tingling sensation of your skin).

- Tremor (involuntary shaking).
- Drowsiness.
- Loss of feeling.
- Abnormal/blurred vision, bloodshot eyes (redness).
- Inflammation of your eyes (pink eyes).
- Cataracts (loss of vision).
- Dry or burning eyes.
- Double vision or loss of vision.
- Tinnitus (ringing in your ears), deafness or ear pain.
- High blood pressure.
- Low blood pressure (light-headedness or dizziness).
- Throat infection (sore throat), sinus infection (blocked or runny nose, headache), lung infection (coughing, fever, increased phlegm), hoarse voice or loss of your voice.
- Increased sputum/phlegm.
- Increased coughing.
- Pain of your stomach area.
- Inflammation of your tongue (swollen, red or tender).
- Difficulty swallowing.
- Inflammation of your stomach (nausea, vomiting or diarrhoea).
- Inflammation of the tube that carries your food to your stomach (heartburn, pain or nausea).
- Inflammation of the inside of your mouth or gums (red, swollen gums, cheeks, or palate).
- Dry mouth.
- Increased sweating.
- Skin ulcerations.
- Sensitivity of your skin to sunlight.
- Arthritis (painful, stiff joints).

- Joint pain or muscle pain.
- Rupture or inflammation of your tendons.
- Muscle weakness.
- Back or bone pain.
- Enlarged breast tissue, abnormal ejaculation or swollen genitals.
- Prostate problems.
- Weakness, overall pain or discomfort.
- Accidental falling and/or injury.
- Swelling of your legs and feet due to water retention.

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

6. STORAGE AND DISPOSING OF SILREXIA

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

7. PRESENTATION OF SILREXIA

Silrexia 25 is packed into silver aluminium foil/colourless transparent PVC film blister strips, in packs of 2 or 4 tablets per blister.

Silrexia 50 is packed into silver aluminium foil/colourless transparent PVC film blister strips, in packs of 2 or 4 tablets per blister.

Silrexia 100 is packed into silver aluminium foil/colourless transparent PVC film blister strips, in packs of 2 or 4 tablets per blister.

8. IDENTIFICATION OF SILREXIA

Silrexia 25: White, oval shaped, biconvex, film coated tablets, plain on one side and debossed with “B9” on the other side.

Silrexia 50: White, oval shaped, biconvex, film coated tablets, plain on one side and debossed with “C1” on the other side.

Silrexia 100: White, oval shaped, biconvex, film coated tablets, plain on one side and debossed with “436” on the other side.

9. REGISTRATION NUMBERS

Silrexia 25: 46/7.1.5/0100

Silrexia 50: 46/7.1.5/0101

Silrexia 100: 46/7.1.5/0102

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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