

SILDENAFIL LUPIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Sildenafil Lupin?

This product contains the active ingredient sildenafil. Sildenafil Lupin is used to treat erectile dysfunction, more commonly known as impotence, in adult males.

For more information, see Section [1. Why am I using Sildenafil Lupin?](#) in the full CMI.

2. What should I know before I use Sildenafil Lupin?

Do not use if you have ever had an allergic reaction or hypersensitivity to sildenafil or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, or take any other medicines.

For more information, see Section [2. What should I know before I use Sildenafil Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with sildenafil and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Sildenafil Lupin?

Your doctor will decide the correct dose for you depending on your condition and response.

Do not take more than one dose of Sildenafil Lupin a day.

More instructions can be found in Section [4. How do I use Sildenafil Lupin?](#) in the full CMI.

5. What should I know while using Sildenafil Lupin?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist, or pharmacist you visit that you are using Sildenafil Lupin.Stop taking this medicine if you have sudden vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes, experience loss of hearing or have an erection that persists for more than 4 hours. Seek medical attention urgently.If you are about to start taking any new medicines, especially nitrates, or riociguat, tell your doctor and pharmacist that you are taking Sildenafil Lupin. |
| Things you should not do | <p>Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are taking Sildenafil Lupin.</p> <p>If you get an angina attack, do not take nitrate medicines to relieve the pain but tell your doctor immediately</p> <p>Do not give this medicine to anyone else, even if they have the same condition as you.</p> |
| Driving or using machines | Do not drive or operate machinery, if you experience changes in vision, or dizziness, when taking Sildenafil Lupin. |
| Drinking alcohol | Be careful drinking alcohol while taking Sildenafil Lupin. Drinking alcohol can temporarily impair the ability to get an erection. |
| Looking after your medicine | Keep Sildenafil Lupin in a cool; dry place where the temperature stays below 30°C. Do not store it in the bathroom or near a sink. Do not leave it in the car or on windowsills. |

For more information, see Section [5. What should I know while using Sildenafil Lupin?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: headache, dizziness, flushing, hot flushes, indigestion, heartburn, nasal or sinus congestion, swelling of your nose, diarrhoea, rash, tightness in your throat, feeling hot or irritable, redness in your mouth or tongue.

Tell your doctor or go straight to the Emergency Department if you notice any of the following: unusual heartbeat, persistent headache or fainting, bleeding from the nose, pain or tingling in your hands, toes or feet, red eye(s), swollen, puffy or pain in or around the eye(s), blood in the urine, sudden vision problems, changes to your normal vision, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, chest pain, increased heart rate, seizures, fits or convulsions or your erection is increased, painful or persists for longer than four hours. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SILDENAFIL LUPIN

Active ingredient: *sildenafil citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sildenafil Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sildenafil Lupin.**

Where to find information in this leaflet:

- [1. Why am I using Sildenafil Lupin?](#)
- [2. What should I know before I use Sildenafil Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Sildenafil Lupin?](#)
- [5. What should I know while using Sildenafil Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Sildenafil Lupin?

This product contains the active ingredient sildenafil citrate. Sildenafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Sildenafil is used to treat erectile dysfunction, more commonly known as impotence, in men. This is when a man cannot get, or keep, a hard-erect penis suitable for sexual activity.

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.

Sildenafil Lupin will work only if you are sexually excited.

Sildenafil Lupin will not increase your sex drive and will work only if you are sexually excited.

Sildenafil Lupin is not for use in women.

This medicine is available only with a doctor's prescription.

2. What should I know before I use Sildenafil Lupin?

Warnings

YOU MUST NOT TAKE SILDENAFIL LUPIN IF YOU ARE TAKING NITRATES OR NITRITE MEDICATIONS. IT MAY LEAD TO A SEVERE DROP IN YOUR BLOOD PRESSURE, WHICH MAY BE DIFFICULT TO TREAT.

BECAUSE SEXUAL ACTIVITY MAY PLACE A STRAIN ON YOUR HEART, YOUR DOCTOR WILL NEED TO CHECK WHETHER YOU ARE FIT ENOUGH TO TAKE SILDENAFIL LUPIN.

Do not use Sildenafil Lupin if:

- you are allergic to sildenafil, or any of the ingredients listed at the end of this leaflet. An allergic reaction can include:
 - hives, itching or skin rash
 - swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing.

Always check the ingredients to make sure you can use this medicine.

- you are being treated for angina (chest pain) or other heart conditions with medicines called nitrates. These are available in multiple dosage forms, such as tablets, patches, sprays and injections. These include but not limited to:

- glyceryl trinitrate (also called nitroglycerin)
- isosorbide mononitrate, isosorbide dinitrate
- nicorandil
- sodium nitroprusside.

- you are taking guanylate cyclase stimulators (GCS), such as riociguat

GCS is a type of medicine used to treat high blood pressure in the blood vessels in the lungs caused by blood clots in the lungs (chronic thromboembolic pulmonary hypertension, CTEPH) or narrowing of the vessels that carry blood from the heart to the lungs (pulmonary arterial hypertension or PAH).

- you have heart or blood vessel problems that make sexual intercourse inadvisable.
- you have suffered a heart attack or stroke in the last 6 months.
- you have severe liver problems.
- you have blood pressure that is unusually high or low or is not effectively treated.
- you have sudden vision problems including loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION).
- you have an eye disease called retinitis pigmentosa.
- the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright.
- the expiry date on the pack has passed. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have any other medical conditions, such as:
 - allergies to any other medicines or any other substances such as foods, preservatives or dyes;

- any other heart or blood vessel problems;
- if you have previously had sudden vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes;
- have any of the following medical conditions:
 - diabetes, especially if you also have eye problems;
 - kidney or liver problems;
 - leukaemia (cancer of the blood cells);
 - multiple myeloma (a cancer of the bone marrow);
 - any disease or deformity of your penis;
 - any bleeding disorder such as haemophilia;
 - a disease of the blood called sickle cell anaemia;
 - stomach ulcer;
 - colour vision problems;
 - if you have previously experienced sudden decrease or loss of hearing;
 - if you take any medicines for impotence.
- are taking any medicines to treat high blood pressure in the vessels of the lungs (pulmonary arterial hypertension) including bosentan or Revatio which also contains sildenafil
- have any other medical conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Sildenafil Lupin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take Sildenafil Lupin if you are taking or using nitrate medicines for angina.

Do not take Sildenafil Lupin if you are taking guanylate cyclase stimulators (GCS), such as riociguat.

Some medicines may interfere with Sildenafil Lupin and affect how it works. This includes

- any medicines to treat high blood pressure in the vessels of the lungs (pulmonary arterial hypertension) including Tracleer (bosentan) or Revatio which also contains sildenafil.
- taking any other treatment for impotence.

Medicines that may increase the effect of Sildenafil Lupin include:

- cimetidine, erythromycin, saquinavir, ketoconazole, itraconazole, and ritonavir.

Medicines that may reduce the effect of Sildenafil Lupin include:

- rifampicin and bosentan.

The effect of medicines that may be greatly increased by Sildenafil Lupin include:

- riociguat, nitrate medicines (for example glyceryl trinitrate), alpha-blockers (for example doxazosin).

You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Sildenafil Lupin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sildenafil Lupin.

4. How do I use Sildenafil Lupin?

How much to take/use

Your doctor will decide the correct dose for you depending on your condition and response. This can be one 25 mg tablet a day or one 50 mg tablet a day or one 100 mg tablet a day. Do not take more than one dose of Sildenafil Lupin a day.

Take Sildenafil Lupin exactly as your doctor has prescribed.

Follow the instructions provided and use Sildenafil Lupin until your doctor tells you to stop.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take/use Sildenafil Lupin

Swallow the tablet whole with a full glass of water.

Sildenafil Lupin should be used about one hour before you intend to have sex.

The amount of time Sildenafil Lupin takes to start working varies from person to person, but it normally takes between half an hour and one hour.

You may find Sildenafil Lupin takes longer to work if you take it with a heavy meal. Sildenafil Lupin will work only if you are sexually excited.

If you use too much Sildenafil Lupin

If you think that you have used too much Sildenafil Lupin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Sildenafil Lupin?

Things you should do

Stop taking Sildenafil Lupin if you have sudden vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes, experience loss of hearing or have an erection that persists for more than 4 hours. Seek medical attention urgently.

If Sildenafil Lupin does not help you get an erection or if your erection does not last long enough to complete sexual intercourse. In these cases, your doctor may decide that you need a higher dose, tell your doctor.

If you are about to start taking any new medicines, especially nitrates, or Adepmas (riociguat), tell your doctor and pharmacist that you are taking Sildenafil Lupin.

See "[2. What should I know before I take Sildenafil Lupin?](#)" for a list of common nitrate medications.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Sildenafil Lupin.

Things you should not do

Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are taking Sildenafil Lupin.

If you get an angina attack (pain in your chest) do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctor knows you are taking Sildenafil Lupin.

Do not give Sildenafil Lupin to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sildenafil Lupin affects you.

Sildenafil Lupin may cause dizziness or changes in vision in some people.

If you experience changes in vision, or dizziness, when taking Sildenafil Lupin, you should not drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful drinking alcohol while taking Sildenafil Lupin.

Drinking alcohol temporarily impair the ability to get an erection.

Do not drink large amounts of alcohol before sexual activity.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or direct sunlight where the temperature stays below 30°C; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep the tablets in their pack until it is time to take them. If you take your tablets out of the pack they will not keep as well.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Nervous system related:</p> <ul style="list-style-type: none"> • Headache. • Dizziness. <p>Vascular related:</p> <ul style="list-style-type: none"> • Flushing. • Hot flushes. <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • Indigestion. • Heartburn. • Diarrhoea. • Dry mouth or dry throat. <p>Respiratory related:</p> <ul style="list-style-type: none"> • Nasal congestion. • Sinus congestion • Dry nose. <p>Skin related:</p> <ul style="list-style-type: none"> • Rash <p>Eye related</p> <ul style="list-style-type: none"> • Dry eye. <p>Other side effects:</p> <ul style="list-style-type: none"> • swelling of your nose. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • Tightness in your throat. • Feeling hot or irritable. • Redness in your mouth or tongue. | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Heart related:</p> <ul style="list-style-type: none"> • unusual heartbeat <p>Urogenital related:</p> <ul style="list-style-type: none"> • urinary tract infection (stinging or burning urine, more frequent need to pass urine) • blood in the urine <p>Nervous system related:</p> <ul style="list-style-type: none"> • persistent headache or fainting • pain or tingling in your hands, toes or feet • decreased sensitivity or numbness in your mouth <p>Eye related:</p> <ul style="list-style-type: none"> • irritation or feeling of having something in the eye • swollen or puffy eye(s) • fatigue, pain in or around the eyes • "red eye" due to swollen blood vessels in the white part of the eye and in the eyelids <p>Other side effects:</p> <ul style="list-style-type: none"> • bleeding from the nose | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

More serious side effects

| More serious side effects | What to do |
|---|------------|
| <p>Allergy related:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts <p>Heart related:</p> <ul style="list-style-type: none"> • chest pain • increased heart rate | |

| | |
|---|---|
| <p>Nervous system related:</p> <ul style="list-style-type: none"> • seizures, fits or convulsions <p>Urogenital related:</p> <ul style="list-style-type: none"> • your erection is increased, painful or persists for longer than usual <p>If your erection continues for four hours, or sooner if there is pain, you should seek medical attention urgently.</p> <p>Eye related:</p> <ul style="list-style-type: none"> • sudden vision problems <ul style="list-style-type: none"> o blurred, decreased or distorted vision o objects appear smaller or further away than they are o changes to colour vision • changes to your normal vision such as: <ul style="list-style-type: none"> o red or yellow colour tinges to your vision or colourless objects appear coloured o you see a halo around lights, sparks or lights when your eyes are closed <p>Rarely, men have lost eyesight after taking drugs to treat erectile dysfunction. If you lose eyesight in one or both eyes or experience changes in vision such as blurring, a blue colour to your vision or a greater awareness of light, seek medical attention urgently.</p> <p>Other side effects:</p> <p>sudden decrease or loss of hearing</p> | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects.</p> |
|---|---|

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Sildenafil Lupin contains

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|---|---|
| Active ingredient (main ingredient) | Sildenafil citrate. |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• Microcrystalline cellulose• Calcium hydrogen phosphate• Croscarmellose sodium• Magnesium stearate• Colloidal anhydrous silica• Hypromellose, titanium dioxide• Lactose monohydrate• Triacetin• Indigo carmine aluminium lake. |
| Potential allergens | Contains lactose monohydrate |

Do not take this medicine if you are allergic to any of these ingredients.

What Sildenafil Lupin looks like

Sildenafil Lupin 50 mg tablets are pale blue to blue, capsule-shaped, film-coated tablets, debossed with 'SL50' on one side and plain on other side (AUST R 355921).

Sildenafil Lupin 100 mg tablets are pale blue to blue, capsule-shaped film-coated tablets, debossed with 'SL100' on one side and plain on other side (AUST R 355925).

They comes in blister packs of 4, 8 or 12 tablets.

* Not all strengths, pack sizes or presentations may be available.

Who distributes Sildenafil Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

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