

Silagra

sildenafil citrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Silagra.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Silagra against the benefits they expect it will have for you.

It should be used only under strict medical supervision.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Silagra is used for

Silagra 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.

Silagra 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.

Silagra will work only if you are sexually excited.

Silagra will not increase your sex drive.

Silagra is not for use in women.

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

Before you take Silagra

YOU MUST NOT TAKE SILAGRA IF YOU ARE TAKING ANY NITRATE MEDICATION. 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 SILAGRA.

When you must not take it

Do not take Silagra if:

1. you are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates.

Nitrate medicines include glyceryl trinitrate (also called nitroglycerin). Common tradenames include tablets; such as Anginine, Lycinate and Nitrostat; patches such as Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran; sprays such as Nitrolingual and Glytrin and injections such as Gliceryl trinitrate concentrate.

Common tradenames for other nitrate preparations include tablets such as ImdurDurules, Monodurdurules, Sorbidin, Isordil, Corangin, ISMO 20, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside.

There may be other tradenames not listed here.

2. you are using amyl nitrite.

3. you have heart or blood vessel problems that make sexual intercourse inadvisable.

4. you have suffered a heart attack or stroke in the last 6 months.

5. you have severe liver problems.

6. your blood pressure is unusually high or low or is not effectively treated.

7. you have loss of vision in one or both eyes from an eye disease called nonarteritic anterior ischaemic optic neuropathy (NAION).

8. you have an eye disease called retinitis pigmentosa.

9. you have an allergy to:

- Silagra or similar medicines

- 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.

10. the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright.

11. the expiry date on the pack has passed.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if:

You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

You have any other heart or blood vessel problems.

You have previously had sudden loss of eyesight in one or both eyes.

You 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
- stomach ulcer
- a disease of the blood called sickle cell anaemia
- colour vision problems
- previously experienced sudden decrease or loss of hearing.

You are receiving any other treatment for impotence.

You 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 Silagra.

Taking other medicines

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

Do not take Silagra if you are using nitrate medicines for angina.

Some medicines and Silagra may interfere with each other. These include:

- cimetidine, a medicine used to treat ulcers
- some medicines used to treat fungal infections including ketoconazole and itraconazole
- some antibiotics including erythromycin and rifampicin
- some protease inhibitors such as ritonavir and saquinavir for the treatment of HIV infection
- medicines called alpha-blockers. These are used to treat high blood pressure or prostate problems.

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 Silagra.

Ask your doctor or pharmacist, if you are not sure if you are taking any of these medicines.

How to take Silagra

Take Silagra exactly as your doctor has prescribed.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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

How much to take

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 Silagra a day.

When to take it

Take your dose of Silagra about one hour before you intend to have sex.

Swallow the tablet whole with a full glass of water.

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

You may find Silagra takes longer to work if you take it with a heavy meal.

Silagra will work only if you are sexually excited.

If you take too much (Overdose)

If you take too much, you are more likely to experience side effects.

Immediately telephone your doctor or Poisons Information Centre in New Zealand (0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much Silagra. Do this even if there are no signs of discomfort.

While you are using it

Things you must do

Stop using Silagra if you have a loss of eyesight in one or both eyes, experienced loss of hearing or have an erection that persists more than 4 hours. Seek medical attention urgently.

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

If you are about to start taking any new medicines, especially nitrates, tell your doctor and pharmacist that you are taking Silagra.

See “Before you take Silagra” for a list of common nitrate medications.

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

Things you must not do

Do not use the drug amyl nitrite (sometimes called “poppers”) while you are taking Silagra.

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctor knows you are taking Silagra.

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

Things to be careful of

Be careful drinking alcohol while taking Silagra.

Drinking alcohol can temporarily impair the ability to get an erection.

Do not drink large amounts of alcohol before sexual activity.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Silagra.

While Silagra helps most people it can cause some unwanted side effects in a few people. All medicines have side effects. If unwanted effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of possible side effects. **You may not get any of them.**

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache, dizziness
- flushing
- indigestion

- nasal congestion
- diarrhoea
- rash.

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

- unusual heart beat
- urinary tract infection (stinging or burning urine, more frequent need to pass urine)
- blood in the urine
- changes in vision such as blurring, a blue colour to your vision or a greater awareness of light
- persistent headache or fainting
- bleeding from the nose.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts
- chest pain
- sudden decrease or loss of hearing
- seizures, fits or convulsions
- Very rarely your erection may persist for longer than usual. If your erection continues for four hours, or sooner if there is pain, you should seek medical attention urgently.
- Rarely men have lost eyesight some time after taking drugs to treat erectile dysfunction (known as impotence). It is not known at this time if Silagra causes this. If you lose eyesight in one or more eyes, seek medical attention urgently.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using Silagra

Storage

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep Silagra where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it 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.

Disposal

If your doctor tells you to stop taking Silagra, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Silagra is available in three strengths:

- Silagra 25 mg - blue, almond shaped, biconvex, film coated tablets, debossed with '25' on one side and plain on other side
- Silagra 50 mg - blue, almond shaped, biconvex, film coated tablets, debossed with '50' on one side and plain on other side
- Silagra 100 mg - blue, almond shaped, biconvex, film coated tablets, debossed with '100' on one side and plain on other side

Ingredients

Active ingredients

- Silagra 25 mg - sildenafil 25 mg
- Silagra 50 mg - sildenafil 50 mg
- Silagra 100 mg - sildenafil 100 mg

Other ingredients

- microcrystalline cellulose
- calcium hydrogen phosphate anhydrous
- croscarmellose sodium
- magnesium stearate
- hypromellose
- film coating material Opadry II -31K80865 Blue (hypromellose, titanium dioxide, lactose monohydrate, triacetin and indigo carmine aluminium lake).

Silagra tablets do not contain gluten.

Distributor

Distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited

Mt. Eden Central Business Park

33a Normanby Road, Mount Eden

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