

SILVASTA®

sildenafil citrate

25 mg, 50 mg and 100 mg film-coated tablets

What is in this leaflet

Please read this leaflet carefully before you start taking Silvasta.

This leaflet answers some common questions about Silvasta. 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 Silvasta against the benefits they expect it will have for you.

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 Silvasta is used for

Silvasta is a treatment for adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

Silvasta 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. Silvasta will work only if you are sexually excited. Silvasta will not increase your sex drive. Silvasta is not for use in women.

This medicine is available with a doctor's prescription or from a trained pharmacist without a doctor's prescription if you meet certain criteria.

Ask your doctor or pharmacist if you have any questions about why Silvasta has been prescribed for you.

Before you take Silvasta

When you must not take it

You must not take Silvasta if you are taking any nitrate medication. It may lead to a severe drop in your blood pressure, which may be difficult to treat. **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.** Nitrates can include glyceryl trinitrate (tablets, patches, oral sprays or injection) or isosorbide 5-nitrate.

Do not take Silvasta if you have been advised to avoid vigorous exercise. Sexual activity may place a strain on your heart, your doctor or pharmacist will need to check whether you are fit enough to take Silvasta.

Do not take Silvasta if you have an allergy to:

- any medicine containing sildenafil citrate, or a class of medicines called phosphodiesterase type 5 inhibitors
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching

Do not take Silvasta if you:

- are being treated with nitrate medication e.g. glyceryl trinitrate, isosorbide 5-nitrate
- are using amyl nitrite ("poppers")

- are taking a class of medicines called guanylate cyclase stimulators, e.g. riociguat
- have heart or blood vessel problems that make sexual intercourse inadvisable
- have recently had a heart attack or stroke, or if you have unusually high or low blood pressure
- have severe liver problems
- have ever had a loss of vision in one or both eyes due to non-arteritic anterior ischaemic optic neuropathy (NAION)
- have certain rare inherited eye diseases such as retinitis pigmentosa

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Silvasta, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if:

1. if you are receiving any other treatment for erectile dysfunction (impotence) or taking medicines for the treatment of pulmonary arterial hypertension (i.e., high blood pressure in the lungs) containing sildenafil or any other PDE5 inhibitor.
2. **you have allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
3. **you have, or have had, the following medical conditions:**
 - heart problems
 - diabetes, especially if you also have eye problems
 - kidney or liver problems
 - sickle cell anaemia (abnormality of red blood cells)
 - leukaemia (cancer of the blood cells)
 - multiple myeloma (cancer of the bone marrow)

- any disease or deformity of your penis
- any bleeding disorder such as haemophilia
- stomach ulcer
- colour vision problems
- previously experienced a sudden decrease or loss of hearing
- previously experienced a sudden loss of vision in one or both eyes

If you have not told your doctor about any of the above, tell them before you start using Silvasta.

Taking other medicines

You must not take Silvasta if you are taking any nitrate medication or if you are taking any guanylate cyclase stimulators e.g. riociguat.

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Silvasta.

Some medicines may interfere with Silvasta. These include:

- cimetidine, a medicine used to treat stomach 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
- medicines used to treat high blood pressure in the blood vessels in the lungs such as bosentan

These medicines may be affected by Silvasta or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Silvasta.

How to take Silvasta

Follow all directions given to you by your doctor or pharmacist carefully.

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.

How much to take

Your doctor or pharmacist 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 halve the tablets.

Do not take more than one dose of Silvasta a day.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take your dose of Silvasta about one hour before you plan to have sex.

Silvasta will only help you get an erection if you are sexually stimulated.

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

Silvasta can be taken with or without food. You may find Silvasta takes longer to work if you take it with a heavy meal.

While you are using Silvasta

Things you must do

If you are about to be started on any new medicine, especially nitrates, tell your doctor and pharmacist that you are taking Silvasta.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

Things you must not do

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

Do not alter the dosage without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Silvasta affects you.

This medicine may cause temporary visual disturbances and dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. Drinking alcohol can temporarily impair your ability to get an erection.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too much Silvasta.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- headache
- dizziness
- flushing
- nasal congestion
- indigestion
- diarrhoea
- rash

The above list includes the more common side effects of your medicine.

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

- unusual heartbeat
- abnormal vision e.g. blurring, increased sensitivity to light, colour tinge to vision

- urinary tract infection (stinging or burning sensation when urinating, greater urgency to urinate)
- blood in urine
- fainting or persistent headache
- nosebleed
- pain or tingling in your hands, toes or feet
- numbness or decreased sensitivity in your mouth
- irritation or feeling of having something in the eye
- puffy or swollen 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

If any of the following happen, stop taking Silvasta and tell your doctor immediately, or go to the Accident and Emergency department 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 of the body
- chest pain
- increased heart rate
- seizures, fit or convulsions
- your erection is increased, painful or 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
- decreased or loss in vision or changes in your normal vision such as yellow or red colour tinges to your vision or halo around lights
- decreased or loss in hearing

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After using Silvasta

Storage

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

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store Silvasta in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Silvasta 25 mg tablets are blue elliptical, biconvex, film-coated tablets, marked "SL25" on one side.

Silvasta 50 mg tablets are blue elliptical, biconvex, film-coated tablets, marked "SL50" on one side.

Silvasta 100 mg tablets are blue elliptical, biconvex, film-coated tablets, marked "SL100" on one side.

All strengths come in a box of 1,2,4,8 and 12 tablets. Not all pack sizes may be marketed.

Ingredients

Silvasta contains 25 mg, 50 mg or 100 mg of sildenafil citrate as the active ingredient.

Inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- povidone
- hypromellose
- titanium dioxide
- indigo carmine
- macrogol 600

Sponsor details

Silvasta is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651

Phone: (09) 835 0660

Date of preparation

19 March 2021
(based on data sheet dated 04 July 2019)