

Consumer Medicine Information

SILVASTA™

25 mg, 50 mg and 100 mg sildenafil tablets

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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 or pharmacist has weighed the risks of you taking Silvasta 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 SILVASTA is used for

Silvasta is used to treat 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.

Before you use SILVASTA

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.

Because 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 been advised to avoid vigorous exercise.

When you must not take it

Do not take Silvasta:

- If you are allergic to sildenafil or any of the other ingredients of Silvasta.

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

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

Do not take Silvasta after the expiry date which is stated on the carton and blister. If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start taking Silvasta, 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 experienced 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
 - sickle cell anaemia (abnormality of red blood cells)
 - leukaemia (cancer of the blood cells)
 - multiple myeloma (cancer of the bone marrow)
 - a deformity of your penis or Peyronie’s Disease
 - any bleeding disorder such as haemophilia
 - stomach ulcer

- colour vision problems
- previously experienced sudden decrease or loss of hearing
- You are receiving any other treatment for impotence
- You are taking treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitor
- 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 Silvasta.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

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

Some medicines and Silvasta may interfere with each other. 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

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. You may need different amounts of your medicine or you may need to take different medicines.

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

How to take SILVASTA

Always take Silvasta exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 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.

You should not take Silvasta more than once a day.

When to take it

Take your dose of Silvasta about one hour before you plan to have sex. Swallow the tablet whole with a full glass of water.

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.

In case of overdose

If you take too much (overdose)

Immediately contact either your doctor, Poisons Information Centre (0800 POISON or 0800 764 766) or accident and emergency department at your nearest hospital if you think that you or anyone else may have taken too many Silvasta tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical treatment.

While you are using SILVASTA

Things you must do

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 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 sexual intercourse, tell your doctor or pharmacist. In these cases, your doctor or pharmacist 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 Silvasta.

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

Things you must not do

Do not take Silvasta if you are using any of the medicines known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may lead to a dangerous fall in blood pressure.

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

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

Things to be careful of

Be careful drinking alcohol while taking Silvasta.

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

To get the maximum benefit from your medicine, do not drink excessive amounts of alcohol before taking Silvasta.

Silvasta can cause dizziness and can affect vision. If you experience changes in vision, or dizziness, when taking Silvasta, you should not drive or operate machinery.

Side effects

Like all medicines, Silvasta can cause side effects although not everyone gets them.

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

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
- nasal congestion
- indigestion
- diarrhoea

- dizziness
- rash

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

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

- unusual heart beat
- 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
- nosebleed

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
- seizures, fits or convulsions
- prolonged erection
- decreased or loss in vision
- decreased or loss in hearing

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

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 below 25°C.

Keep this medicine out of reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not store Silvasta or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Disposal

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

Product Description

What it looks like

Silvasta Tablets are available in three strengths:

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

Active ingredients

Silvasta 25 mg - sildenafil (as citrate) 25 mg

Silvasta 50 mg - sildenafil (as citrate) 50 mg

Silvasta 100 mg - sildenafil (as citrate) 100 mg

Other ingredients

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, povidone K29-32, hypromellose, titanium dioxide, indigo carmine aluminium lake (E171), macrogol 6000

Supplier

Silvasta is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

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New Zealand

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