

SILARAN

Sildenafil (as citrate) 100 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SILARAN.

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 SILARAN against the benefits it is expected to 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 SILARAN is used for

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

Sildenafil citrate belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by relaxing the blood vessels in the penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection naturally.

SILARAN will only work if you are sexually excited. It will not increase your sex drive.

SILARAN is not for use in women.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you take SILARAN

YOU MUST NOT TAKE SILARAN 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 SILARAN.

When you must not take SILARAN

Do not take SILARAN if:

- you have or have ever had an allergy to sildenafil or any of the ingredients of SILARAN listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

- you are being treated for angina (pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back). Nitrate medicines including glyceryl trinitrate (also called nitroglycerin, such as: ANGININE or LYCINATE tablets; NITRO-DUR, TRANSIDERM-NITRO and MINITRAN patches; NITROLINGUAL spray); isosorbide nitrates such as: IMDUR, SORBIDIN, MONODUR and DURIDE tablets. There may be other brands not listed above.
- you are taking amyl nitrite (also known as poppers)
- you are taking sodium nitroprusside
- you have heart or blood vessel problems that makes sexual intercourse inadvisable
- you have suffered a heart attack or stroke in the last 6 months
- you have severe liver problems
- your blood pressure is unusually high or low and is not being treated effectively
- you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION). This disease arises from damage to the optic nerve due to lack of blood supply.
- you have an eye disease called retinitis pigmentosa. This is a genetic disease which is characterised by tunnel vision and night blindness.
- if the packaging is torn or shows signs of tampering, or after the expiry date printed on the pack has passed. If it has expired or is damaged, it may not work as well.

If you are not sure whether to start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

- you have any allergy to any other medicines or any other substances, such as foods, preservatives or dyes
- you have or have had problem(s) with your heart or blood vessels
- you have problem(s) with your liver or kidney(s)
- you have previously had sudden loss of eyesight in one or both eyes
- you suffer from any of the following conditions:
 - sugar diabetes, especially if you also have eye problems
 - leukaemia (cancer of the blood)
 - multiple myeloma (cancer of the bone marrow)
 - sickle cell anaemia
 - any disease or deformity of your penis
 - bleeding problem (such as haemophilia)
 - stomach ulcer
 - problems with your colour vision
- you have had previously experienced sudden decrease or loss of hearing which may or may not be accompanied with ringing in the ears and dizziness
- you are taking any other medicine for treatment for impotence

If you have not told your doctor about any of the above, tell him/her before you take SILARAN.

Taking other medicines

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

Some medicines and SILARAN may interfere with or affect how each other works. These include:

- cimetidine (used to treat ulcers)
- some medicines used to treat fungal infections, including ketoconazole and itraconazole
- some antibiotics including erythromycin and rifampicin
- some medicines used to treat HIV including ritonavir and saquinavir
- doxazosin or medicines called alpha blockers, which are used in the treatment of high blood pressure or prostate problems

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines. You may need different amounts of your medicines 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take SILARAN

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

These instructions may differ from the information contained in this leaflet.

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

How much to take

Take SILARAN exactly as your doctor has prescribed. The usual dose of sildenafil is between 25-100 mg taken once a day.

Your doctor may prescribe a lower dose of SILARAN for you if you are elderly, or if you have kidney or liver problems.

Do not take more than one dose of SILARAN in a day.

How to take it

Swallow SILARAN whole with a full glass of water.

When to take it

Take your dose of SILARAN, as advised by your doctor, one hour before you intend to have sex.

The length of time it takes for SILARAN to start acting varies from person to person. Normally it takes between half an hour to one hour.

You may find that SILARAN takes longer to act if you take it with a heavy meal.

SILARAN will work only if you are sexually excited.

If you take too much (overdose)

If you are taking more than the recommended dose of SILARAN, you are more likely to experience side effects.

Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much SILARAN.

Do this even if there are no signs of discomfort. You may need urgent medical attention. Keep telephone numbers of these facilities handy.

While you are taking SILARAN

Things you must do

You must stop using SILARAN if:

- You suffer a loss of eyesight in one or both eyes
- You experience loss of hearing
- You have an erection that persists for more than 4 hours

If you experience any of the above while taking SILARAN, you need to seek medical attention urgently.

Tell your doctor in case SILARAN does not help you get an erection or if your erection does not last long enough to complete sexual intercourse. In such cases, your doctor may recommend a higher dose.

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Things you must not do

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

Do not use SILARAN to treat any other complaints unless your doctor tells you to.

If you have an angina attack, do not take nitrate medicines but tell your doctor immediately, and tell him/her that you are taking SILARAN.

Things to be careful of

Be careful drinking alcohol while taking SILARAN.

Alcohol can temporarily affect the ability to get an erection. Avoid drinking large quantities of alcohol before sexual activity.

If you experience dizziness or change in vision when taking SILARAN, do 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 SILARAN.

SILARAN helps most people suffering from erectile dysfunction (or impotence), but it may have unwanted side effects in a few people. 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 side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

- headache
- flushing
- an uncomfortable feeling in the stomach or belching after eating
- nasal congestion
- diarrhoea
- dizziness
- rash

These side effects are more common and are usually mild and short-lived.

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

- unusual heart beat
- urinary tract infection (stinging or burning sensation, need to pass urine more frequently)
- blood in the urine
- changes in vision such as blurring, a blue tinge to your vision or being more sensitive to light
- persistent headache or fainting
- bleeding from the nose

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happens, 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 in breathing, swelling of the face, lips, tongue or other parts of the body
- chest pain
- sudden decrease or loss of hearing
- seizures, fits or convulsions
- 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. This very rarely happens.
- men have lost eyesight some time after taking drugs to treat erectile dysfunction (or impotence) on rare occasions. It is not known at this time if SILARAN causes this. If you lose eyesight in one or more eyes, seek medical attention urgently.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

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

After taking SILARAN

Storage

Keep SILARAN in a cool, dry place 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 window sills. Heat and dampness can destroy some medicines.

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 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 SILARAN or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What SILARAN looks like

SILARAN is only available as a 100 mg tablet. The 25 mg and 50 mg tablet strengths are offered by other brand.

SILARAN 100 mg tablets are red, rounded triangular-shaped, film-coated tablets, with 'S23' engraved on one side and plain on the other side.

Available in a box of 4 tablets.

Ingredients

Active ingredient:

SILARAN 100 mg tablets - sildenafil citrate equivalent to 100 mg of sildenafil

Inactive ingredients:

- microcrystalline cellulose
- anhydrous calcium hydrogen phosphate
- croscarmellose sodium
- magnesium stearate
- hypromellose
- brilliant scarlet 4R aluminium lake
- macrogol 400
- titanium dioxide
- iron oxide red
- indigo carmine aluminium lake

SILARAN tablets do not contain gluten, lactose or other sugars.

Sponsor

Ranbaxy Australia Pty Ltd
9-13 Waterloo Road
Macquarie Park NSW 2113

Australian Registration Number

SILARAN 100 mg tablets: AUST R 196242

This leaflet was prepared in July 2013.