

Sidena 50 mg Tablets

sildenafil

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

- Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have taken Sidena as directed and were not able to get or keep an erection firm enough for sex.

What is in this leaflet

1. What Sidena is and what it is used for
2. What you need to know before you take Sidena
3. How to take Sidena
4. Possible side effects
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1 What Sidena is and what it is used for

Sidena contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Sidena will only help you to get an erection if you are sexually stimulated.

Sidena is a treatment for adult men with erectile dysfunction.

Erectile dysfunction, also known as impotence, is an inability to achieve or maintain an erection that is firm enough to have sex. Erections depend on many different factors, including proper blood flow to the penis. Reduced blood flow to the penis may cause erectile dysfunction. Erectile dysfunction can affect men differently. Some cannot achieve an erection. Others may achieve an erection, but not firm enough for having sex or they may lose the erection before or during sex.

2 What you need to know before you take Sidena

Do not take Sidena:

- if you do not have an erection problem
- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)
- if you have low blood pressure (below 90/50mmHg) which can cause symptoms such as tiredness, dizziness, light-headedness, feeling sick, clammy skin, depression, loss of consciousness or blurry vision
- if you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. 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.
- if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a dangerous fall in your blood pressure
- if you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e. high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e. high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Sidena have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- if you have a severe heart or liver problem
- if you have recently had a stroke or a heart attack, or if you have low blood pressure
- if you have certain rare inherited eye diseases (such as *retinitis pigmentosa*)
- if you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION)
- if you have a deformed penis
- if you are a woman
- if you are under 18 years of age.

Warnings and precautions

You should schedule a health check-up with your doctor as soon as possible within the first 6 months of starting to use Sidena to ensure that your erection problems are not caused by any serious health condition.

Erectile dysfunction may be an early sign of:

- cardiovascular disease
- diabetes
- high blood pressure
- high cholesterol

Tell your doctor about your problems if you have not already done so.

Cardiovascular risk factors

Sexual activity can put a strain on your heart (see "Do not take Sidena if you" above).

Talk to your doctor before taking Sidena if you:

- get very breathless or feel any pain in the chest with light or moderate activity (e. g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have a problem with a valve in your heart (valvular heart disease)
- have a disease in which the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy)
- have an irregular heartbeat (arrhythmia)
- you have had surgery to improve blood flow to your heart, or you have high blood pressure which is now adequately treated
- have high blood pressure that is not controlled.

Other risk factors:

Talk to your doctor before taking Sidena if you:

- have ever had an erection that lasted more than 4 hours (priapism). Some conditions can increase the probability of having a persistent erection, such as sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow). Use of impotence medicines may increase the risk of priapism. Long lasting erection may cause damage to the tissue of the penis and permanent loss of ability to have an erection.
- have a stomach ulcer or a bleeding disorder (such as haemophilia).
- have previously been diagnosed with mild to moderate liver disease, or severe kidney problems. Sidena may not be suitable for you, you should consult your doctor before taking Sidena.

If you experience any sudden visual defect you should stop taking Sidena and contact your doctor immediately. Cases of visual effects have been reported when using sildenafil.

You should not use Sidena with any other oral or

local treatments for erectile dysfunction.

You should not use Sidena with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

Sidena should not be given to individuals under the age of 18.

Other medicines and Sidena

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Sidena tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken Sidena and when you did. Do not take Sidena with other medicines unless your doctor tells you that you can. Do not use Sidena if you take:

- **Nitrate medicines:** Do not take Sidena if you are taking nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) against chest pain (*angina pectoris*) or heart failure or "poppers" as recreational drugs (nitric oxide donors (such as amyl nitrite), nicorandil or sodium nitroprusside). This is because these substances could lead to a dangerous fall in blood pressure if taken together with Sidena.
 - **Riociguat:** Do not take Sidena if you are taking a medicine called riociguat (or other medicines of a group called guanylate cyclase stimulators). Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Sidena.
 - **Medicines to treat HIV-infections: Ritonavir** is a medicine used to treat HIV-infections. Do not take Sidena if you are taking ritonavir since this combination can lead to a dangerous fall in blood pressure.
- Talk to your pharmacist or doctor before using Sidena if you are taking:
- **Medicines to treat fungal infections and antibiotics:** Medicines to treat fungal infections called itraconazole or ketoconazole and an antibiotic called erythromycin increase the concentration of Sidena in the body and may result in side effects. You should contact your doctor before taking Sidena if you are using these medicines.
 - **Heartburn treatment:** The medicine to treat heartburn, cimetidine, increases the concentration of Sidena in the body and may result in side effects. You should contact your doctor before taking Sidena.
 - **Other treatments for erectile dysfunction:** The safety and efficacy of combinations of Sidena with other treatments for erectile dysfunction have not been studied and this combination is therefore not recommended.
 - **Alpha-blockers used to treat urinary problems or high blood pressure:** Alpha-blockers used to treat urinary problems due to enlarged prostate (such as alfuzosin, doxazosin or tamsulosin) may lead to dizziness, light-headedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
 - **Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines containing sacubitril/valsartan, used to treat heart failure.**

Sidena with food and drink and alcohol

Sidena can be taken with or without food. However, you may find that Sidena takes longer to start working if you take it with a heavy meal.

Do not take Sidena with grapefruit or grapefruit juice, because this can affect how the medicine works.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking Sidena.

Pregnancy, breast-feeding and fertility

Sidena is not indicated for use by women.

Driving and using machines

Sidena can cause dizziness and can affect vision. You should be aware of how you react to Sidena before you drive or use machinery. Do not drive or use machines if you suffer from these side effects after taking this medicine.

Sidena contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Sidena

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor have told you. Check with your pharmacist or doctor if you are not sure.

- Take 1 tablet, as needed, approximately 1 hour before sexual activity.
- Swallow the tablet whole with water.
- Do not take more than 1 tablet a day.

Sidena will only help you achieve an erection if you are sexually aroused. You and your partner should engage in foreplay just as you would if you were not taking a medicine for erectile dysfunction. The amount of time this medicine takes to work varies from person to person, but it normally takes between 30 to 60 minutes. You may take it up to 4 hours before sexual activity.

Relax and be patient if Sildenafil does not help you the first time. You can try again later but remember you can only take 1 tablet a day. For most men, Sildenafil will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you achieve the desired effect. Talk to your doctor if you have tried Sildenafil and are still not able to get and keep an erection.

If you feel the effect of Sildenafil is too strong, talk to your pharmacist or doctor.

Do not take Sildenafil tablets in combination with sildenafil containing orodispersible medicines.

Sildenafil 50 mg

The tablet can be divided into four equal doses. You have to take at least two quarters (corresponding to 25 mg) to reach the minimum effective dose.

Dividing the tablets

Place the tablet on a hard, flat surface with the scoreline facing upwards. Press with your thumb on the middle of the tablet and the tablet breaks into four equal doses.

If you take more Sildenafil than you should

If you take more tablets than recommended, contact your pharmacist or doctor immediately. Taking more than the recommended dose may result in side effects and/or more severe side effects.

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of Sildenafil are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil and seek medical help immediately:

- An allergic reaction - this occurs uncommonly (may affect up to 1 in 100 people)
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- Chest pains - this occurs uncommonly
If this occurs during or after intercourse
- Get in a semi-sitting position and try to relax.
- **Do not use nitrates** to treat your chest pain.
- Prolonged and sometimes painful erections - this occurs rarely (may affect up to 1 in 1,000 people)
If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.
- A sudden decrease or loss of vision - this occurs **rarely**
- Serious skin reactions - this occurs **rarely**
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits - this occurs **rarely**

Other side effects:

Very common (may affect more than 1 in 10 people):

- headache.

Common (may affect up to 1 in 10 people):

- nausea
- facial flushing
- hot flush (symptoms include a sudden feeling of heat in your upper body)
- indigestion
- colour tinge to vision, blurred vision, visual disturbance
- stuffy nose
- dizziness.

Uncommon (may affect up to 1 in 100 people):

- vomiting
- skin rash
- eye irritation, bloodshot eyes /red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes
- pounding heartbeat, rapid heartbeat
- high blood pressure, low blood pressure
- muscle pain
- feeling sleepy
- reduced sense of touch
- vertigo
- ringing in the ears
- dry mouth
- blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose)
- upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn)
- presence of blood in urine
- pain in the arms or legs
- nosebleed
- feeling hot
- feeling tired.

Rare (may affect up to 1 in 1,000 people):

- fainting
- stroke, heart attack, irregular heartbeat
- temporary decreased blood flow to parts of the brain
- feeling of tightening of the throat
- numb mouth
- bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye
- penile bleeding
- presence of blood in semen
- dry nose, swelling of the inside of the nose
- feeling irritable
- sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Sildenafil.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance.

Website: www.hpra.ie; By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Sildenafil

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Sildenafil after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and further information

What Sildenafil contains

- The active substance is sildenafil. Each tablet contains 50 mg of sildenafil (as citrate).
- The other ingredients are: calcium hydrogen phosphate anhydrous, microcrystalline cellulose, copovidone, croscarmellose sodium, magnesium stearate, saccharin sodium, indigo carmine aluminium lake (E132).

What Sildenafil looks like and contents of the pack

Sildenafil 50 mg Tablet is a light blue, round, slightly dotted tablet with cross breaking notch on one side and an imprint of "50" on the other side.

Sildenafil is available in blister packs with, 2, 4 & 8 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

S.C. Sandoz S.R.L., 7A Livezeni Street, 540472

Targu Mures, Jud. Mures, Romania.

Lek S.A., ul. Domaniewska 50 C, 02-672,

Warszawa, Poland.

Lek Pharmaceuticals d.d., Trimlini 2 D, 9220

Lendava, Slovenia.

This medicinal product is authorized in the Member States of the EEA under following names:

Ireland Sildenafil 50 mg Tablets

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