

## Package leaflet: Information for the patient

**Sildenafil**  
**Sildenafil 25 mg Tablets**  
**Sildenafil 50 mg Tablets**  
**Sildenafil 100 mg Tablets**

Sildenafil



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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take Sildenafil 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 medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Sildenafil.

**What is in this leaflet:**

1. What Sildenafil is and what it is used for
2. What you need to know before you take Sildenafil
3. How to take Sildenafil
4. Possible side effects
5. How to store Sildenafil
6. Contents of the pack and other information

## 1 What Sildenafil is and what it is used for

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

Sildenafil 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.

## 2 What you need to know before you take Sildenafil

**Do not take Sildenafil**

- if you are allergic to sildenafil or any other ingredients of this medicine (listed in section 6).
- 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 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).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Sildenafil

- if you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- if you have a deformity of your penis or Peyronie's Disease.
- if you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex
- if you currently have a stomach ulcer, or a bleeding disorder (such as haemophilia)
- if you experience sudden decrease or loss of vision, stop taking Sildenafil and contact your doctor immediately.

You should not take Sildenafil if you do not have erectile dysfunction. You should not take Sildenafil if you are a woman.

**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**

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

**Other medicines and Sildenafil**

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

Sildenafil 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 Sildenafil and when you did. Do not take Sildenafil with other medicines unless your doctor tells you that you can.

You should not take Sildenafil if you are taking medicines called nitrates, as the combination of these medicines may lead to a potentially dangerous fall in your

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Sildenafil with alpha-blockers. This is most likely to happen within 4 hours after taking Sildenafil. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil. Your doctor may start you on a lower dose (25 mg) of Sildenafil.

**Sildenafil with food and drink and alcohol**

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

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 Sildenafil.

**Pregnancy, breast-feeding and fertility**

Sildenafil is not indicated for use by women.

**Driving and using machines**

Sildenafil can cause dizziness and can affect vision. You should be aware of how you react to Sildenafil before you drive or use machinery.

## 3 How to take Sildenafil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is 50 mg.

**You should not take Sildenafil more than once a day**

You should take Sildenafil about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

**Sildenafil 25 mg:**

The scoreline is only to facilitate breaking for ease of swallowing.

**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 equal halves.

**Sildenafil 50 mg:**

The tablet can be divided into equal quarters. 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 equal quarters.

**Sildenafil 100 mg:**

The tablet can be divided into equal quarters.

**Dividing the tablets**

Place the tablet on a hard, flat surface with the deeper scoreline facing upwards. Press with your thumb on the middle of the tablet and the tablet breaks into equal quarters. If you have the feeling that the effect of Sildenafil is too strong or too weak, talk to your doctor or pharmacist.

Sildenafil will only help you to get an erection if you are sexually stimulated. The amount of time Sildenafil takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Sildenafil takes longer to work if you take it with a heavy meal.

If Sildenafil does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

**If you take more Sildenafil than you should**

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

**You should not take more tablets than your doctor tells you to.**

continued on the next page >>



Contact your doctor if you take more tablets than you should.

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 rarely)  
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 (frequency unknown). 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 (frequency unknown).
- Serious skin reactions (frequency unknown). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eye, fever.
- Seizures or fits (frequency unknown)

### Other side effects

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

**Common** (may affect up to 1 in 10 people): facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

**Uncommon** (may affect up to 1 in 100 people): vomiting, skin rash, bleeding at the back of the eye, bloodshot eyes/red eyes, eye irritation, eye pain, double vision, abnormal sensation in the eye, watery eyes, pounding heartbeat, rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/urine, chest pain and feeling tired.

**Rare** (may affect up to 1 in 1,000 people): high blood pressure, low blood pressure, fainting, stroke, heart attack, irregular heart beat, nosebleed and sudden decrease or loss of hearing.

**Not known** (frequency cannot be estimated from the available data):  
Additional side effects reported from post-marketing experience:  
Unstable angina (a heart condition), sudden death, temporary decreased blood flow to parts of the brain.

Most, but not all of these men 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Sildenafil

Keep 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 label. 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 to protect the environment.

## 6 Further information

### What Sildenafil contains

The active substance is sildenafil.

Each tablet contains 25 mg/50 mg/100 mg of sildenafil (as the citrate salt).

The other ingredients are: calcium hydrogen phosphate anhydrous, microcrystalline cellulose, copovidone, croscarmellose sodium, magnesium

stearate, saccharin sodium, indigo carmine aluminium lake (E 132).



### What Sildenafil looks like and contents of the pack

#### Sildenafil 25 mg tablets

Sildenafil 25 mg tablets are light blue round slightly dotted tablets, with breaking notch on one side and embossment "25" on the other side.

#### Sildenafil 50 mg tablets

Sildenafil 50 mg tablets are light blue round slightly dotted tablets, with cross breaking notch on one side and embossment "50" on the other side.

#### Sildenafil 100 mg tablets

Sildenafil 100 mg tablets are light blue round slightly dotted tablets, with cross breaking notch on both sides and embossment "100" on one side.

Sildenafil is available in blister packs with 1, 2, 4, 6, 8, 10, 12, 16, 20, 24 or 28 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturers

**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.  
Salutas Pharma GmbH, Dieselstr. 5, 70839 Gerlingen, 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.

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

The Netherlands	Sildenafil 25 mg, tabletten Sildenafil 50 mg, tabletten Sildenafil 100 mg, tabletten
Ireland	Sildenafil 25 mg Tablets Sildenafil 50 mg Tablets Sildenafil 100 mg Tablets

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# Artwork Checklist

**Job Description**  
Sildenafil 25 mg, 50 mg & 100 mg Tablets  
PIL renewal

**Version Number**  
4

**Size**  
130 x 540

**Inks**  

Colour	black
Prints On Front	✓
Prints On Back	✓

**ACCF**

**Cutter Ref.**  
N/A

**Proof Date**  
29/7/2014

**Market**  
IM