



PACKAGE LEAFLET: INFORMATION FOR THE USER

Sildenafil 25 mg film-coated tablets
Sildenafil 50 mg film-coated tablets
Sildenafil 100 mg film-coated tablets
 (Sildenafil citrate)

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 or pharmacist.
 • 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

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

Sildenafil is a treatment for 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 of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease 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 drugs known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to Sildenafil or any of the other ingredients of Sildenafil.
- 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 a loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

- Talk to your doctor 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 in that case carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problem (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildenafil and contact your doctor immediately.

You should not use Sildenafil with any other oral or local treatment for erectile dysfunction.

Children and adolescents

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

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.

Other medicines and Sildenafil

Tell your doctor or pharmacist if you are taking, 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 any healthcare professional treating your condition 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 products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist 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 drugs known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may lead to a potentially dangerous decrease 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.

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 occur within 4 hours after taking Sildenafil. In order to reduce the likelihood that these symptoms occur, 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, 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 and breast-feeding

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.

Sildenafil contains tartrazine

May cause allergic reactions as it contains Tartrazine (E-102). It can worsen asthma.

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600 mm

600 mm

140 mm

140 mm

3. How to take Sildenafil

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

The usual 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.

If you have the impression 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.

Do not take more tablets than your doctor tells you to.

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

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 short duration.

If you have chestpains during or after intercourse:

- Get in a semi-sitting position and try to relax.
- Do not use nitrates to treat your chest pain.
- Contact your doctor immediately.

All medicines including Sildenafil can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Sildenafil: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking Sildenafil. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking Sildenafil and contact your doctor immediately.

A very common side effect (may affect more than 1 in 10 people) is headache.

Common side effects (may affect up to 1 in 10 people) include: 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 side effects (may affect up to 1 in 100 people) include: vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes (red eyes), eye pain, double vision, abnormal sensation in the eye, watery eyes, irregular or 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/or urine, chest pain and feeling tired.

Rare side effects (may affect up to 1 in 1,000 people) include: high blood pressure, low blood pressure, fainting, stroke, heart attack, nosebleed, sudden decrease or loss of hearing and non-arteritic anterior ischaemic optic neuropathy.

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death, temporary decrease in 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. Cases of convulsions or seizures and serotonin reactions characterised by rash, blister, peeling skin and pain which require immediate medical attention have also been reported.

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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard 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 temperature storage conditions.

Do not use this medicine after the expiry date which is stated on the carton. 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. Contents of the pack and other information

What Sildenafil contains

The active substance is sildenafil.
 Each film-coated tablet contains 25 mg of sildenafil, as the citrate.
 Each film-coated tablet contains 50 mg of sildenafil, as the citrate.
 Each film-coated tablet contains 100 mg of sildenafil, as the citrate.

The other ingredients are:

- Tablet core: cellulose powder, colloidal silicon (anhydrous), calcium phosphate dibasic (anhydrous), croscarmellose sodium, magnesium stearate.
- Film coat: hypromellose, titanium dioxide (E171), triacetin, indigotine aluminium lake (E132), brilliant blue aluminium lake (E133), tartrazine aluminium lake (E102)

What Sildenafil looks like and contents of the pack

Sildenafil film-coated tablets are blue, circular and convex tablets. The tablets are provided in blister packs containing 2, 4, 8 or 12 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
 Strandhaven Ltd t/a Somex Pharma
 630 High Road, Seven Kings, Ilford, Essex, IG3 8BS, United Kingdom

Manufacturer:
 Strandhaven Limited t/a Somex Pharma, Ilford, Essex IG3 8RA

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

Name of the Member State	Sildenafil 25 mg film-coated tablets
	Sildenafil 50 mg film-coated tablets
	Sildenafil 100 mg film-coated tablets

This leaflet was last revised in 10/2014

PL 220946

Product Specification		Packaging		Packaging		Packaging	
Sildenafil 50 mg film-coated tablets		Sildenafil 25 mg film-coated tablets		Sildenafil 100 mg film-coated tablets		Sildenafil 25 mg film-coated tablets	
Packaging Code: 1 x 4 Tab		Packaging Code: 1 x 4 Tab		Packaging Code: 1 x 4 Tab		Packaging Code: 1 x 4 Tab	
Developed on: 03-07-2013		Developed on: 03-07-2013		Developed on: 03-07-2013		Developed on: 03-07-2013	
Location	Colgate, Breda	Location	Colgate, Breda	Location	Colgate, Breda	Location	Colgate, Breda
Blister Size	1 x 140 mm x 11 800 mm; Filling Size: 1 x 600/17, 6mm	Blister Size	1 x 140 mm x 11 800 mm; Filling Size: 1 x 600/17, 6mm	Blister Size	1 x 140 mm x 11 800 mm; Filling Size: 1 x 600/17, 6mm	Blister Size	1 x 140 mm x 11 800 mm; Filling Size: 1 x 600/17, 6mm
Reference	PL 220946-00	Reference	PL 220946-00	Reference	PL 220946-00	Reference	PL 220946-00
Formulation	Tablet	Formulation	Tablet	Formulation	Tablet	Formulation	Tablet
Excipients	*	Excipients	*	Excipients	*	Excipients	*
Colour	Black	Colour	Black	Colour	Black	Colour	Black
Strength	50 mg	Strength	25 mg	Strength	100 mg	Strength	25 mg
Substrate	Front - Back Printing	Substrate	Front - Back Printing	Substrate	Front - Back Printing	Substrate	Front - Back Printing
Marking	-	Marking	-	Marking	-	Marking	-
Manufacturer	Strandhaven Ltd t/a Somex Pharma	Manufacturer	Strandhaven Ltd t/a Somex Pharma	Manufacturer	Strandhaven Ltd t/a Somex Pharma	Manufacturer	Strandhaven Ltd t/a Somex Pharma
Production	UK	Production	UK	Production	UK	Production	UK
Quality	Good	Quality	Good	Quality	Good	Quality	Good
Stability	Good	Stability	Good	Stability	Good	Stability	Good
Biocompatibility	Good	Biocompatibility	Good	Biocompatibility	Good	Biocompatibility	Good
Other	Good	Other	Good	Other	Good	Other	Good
Compliance	Good	Compliance	Good	Compliance	Good	Compliance	Good
Approval	Good	Approval	Good	Approval	Good	Approval	Good
Marketing	Good	Marketing	Good	Marketing	Good	Marketing	Good
Production	Good	Production	Good	Production	Good	Production	Good