

Sildenafil Pfizer® 100mg film-coated tablets

Ref: 117/002/170414/1/F

(sildenafil)

Patient Information Leaflet

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

Your medicine is called Sildenafil Pfizer 100mg film-coated tablets but will be referred to as Sildenafil Pfizer throughout this leaflet.

Please note that the leaflet also contains information about other strengths of the medicine, Sildenafil Pfizer 25mg film-coated tablets and Sildenafil Pfizer 50mg film-coated tablets

In this leaflet:

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

Sildenafil Pfizer contains the active substance sildenafil (as citrate), 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. This medicine will only help you to get an erection if you are sexually stimulated.

This medicine 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 Pfizer

Do not take Sildenafil Pfizer

- * 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 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 Pfizer
- * 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 problem (such as haemophilia).
 - * If you experience sudden decrease or loss of vision, stop taking this medicine and contact your doctor immediately.

You should not use this medicine with any other oral or local treatments for erectile dysfunction.

You should not take Sildenafil Pfizer if you do not have erectile dysfunction.

You should not take Sildenafil Pfizer 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

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

Other medicines and Sildenafil Pfizer

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

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

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

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 Pfizer with alpha-blockers. This is most likely to happen within 4 hours after taking this medicine. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start this medicine. Your doctor may start you on a lower dose (25 mg) of this medicine.

Sildenafil Pfizer with food, drink and alcohol

This medicine can be taken with or without food. However, you may find that this medicine 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 this medicine.

Pregnancy, breast-feeding and fertility

This medicine is not indicated for use by women.

Driving and using machines

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

Sildenafil Pfizer contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3 How to take Sildenafil Pfizer

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 Pfizer more than once a day.

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

If you feel that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

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

If this medicine 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.

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Patient Information Leaflet (continued)

If you take more Sildenafil Pfizer 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.

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 this medicine are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil Pfizer 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 eyes, 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, eye irritation, bloodshot eyes /red eyes, 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/or 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 heartbeat, 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 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 this medicine.

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 IMB Pharmacovigilance Section, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Sildenafil Pfizer

Keep out of the sight and reach of children.

Do not store above 30°C.

Store in the original package to protect from moisture.

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

What Sildenafil Pfizer contains

The active substance is sildenafil. Each tablet contains 100 mg of sildenafil (as the citrate salt).

The other ingredients are:

Tablet core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate.

Film coat: hypromellose, lactose (see section 2 "Sildenafil Pfizer contains lactose"), triacetin, titanium dioxide (E171).

What Sildenafil Pfizer looks like and contents of the pack

Sildenafil Pfizer 100 mg film-coated tablets are white to off-white, with a rounded-diamond shape and they are marked "100" on one side.

The tablets are provided in blister packs containing 4 tablets in a carton.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Pfizer PGM, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

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

Austria	Sildenafil Pfizer 25 (50 or 100 mg) Filmtabletten
Belgium	Sildenafil Pfizer
Cyprus	Sildenafil Pfizer
Czech Republic	Sildenafil Pfizer 25 (50 or 100 mg) potahované tablety
Denmark	Sildenafil Pfizer
Estonia	Sildenafil Pfizer 50 mg õhukese polümeerikattega tabletid Sildenafil Pfizer 100 mg õhukese polümeerikattega tabletid
Finland	Sildenafil Pfizer
France	SILDENAFIL PFIZER, 25 (50 or 100 mg) comprimé pelliculé
Germany	Sildenafil Pfizer 25 (50 or 100 mg) Filmtabletten
Greece	Sildenafil Pfizer
Hungary	Sildenafil Pfizer 25 (50 or 100 mg) filmtableta
Iceland	Sildenafil Pfizer
Ireland	Sildenafil Pfizer 25 (50 or 100 mg) film-coated tablets
Italy	Sildenafil Pfizer
Latvia	Sildenafil Pfizer 50 mg apvalkotās tabletes Sildenafil Pfizer 100 mg apvalkotās tabletes
Luxembourg	Sildenafil Pfizer
Malta	Sildenafil Pfizer 25 (50 or 100 mg) Film Coated Tablets
Netherlands	Sildenafil Pfizer 25 (50 or 100 mg) filmomhulde tabletten
Norway	Sildenafil Pfizer
Poland	Sildenafil Pfizer
Portugal	Sildenafil Pfizer
Romania	Sildenafil Pfizer 25 mg (50, 100 mg) comprimate filmate
Spain	Sildenafil Pfizer 25 mg (50 mg, 100 mg) comprimidos recubiertos con película EFG
Slovenia	Sildenafil Pfizer 25 (50 or 100 mg) filmsko obložene tablete
Slovakia	Sildenafil Pfizer 50 or 100 mg filmom obalené tablety
Sweden	Sildenafil Pfizer
United Kingdom	Sildenafil 25 (50 or 100 mg) film-coated tablets

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

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for help.