

Package leaflet: Information for the patient

Sildenafil 50mg film-coated 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, or 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Sildenafil Tablets is and what it is used for

The full name of your medicine is Sildenafil 50mg film-coated tablets, but within this leaflet it will be referred to as Sildenafil Tablets.

Sildenafil Tablets is a treatment for adult men (aged 18 years and older) with erectile dysfunction (also known as impotence). This is when a man cannot get, or keep an erection hard enough for satisfactory sexual activity.

Erections depend on many things, including proper blood flow to the penis. If blood cannot flow adequately to the penis, it can cause erectile dysfunction. Erectile dysfunction is a common problem and can affect men differently. Some men cannot get an erection, other men can get an erection but it may not be hard enough for sex, or they may lose their erection before or during sex.

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

2. What you need to know before you take Sildenafil Tablets

Do not take Sildenafil Tablets if you:

- **do not have an erection problem, as this medicine will not provide any benefit to you;**
- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6);
- **are taking medicines called nitrates** or nitric oxide donors (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate for the relief of chest pain, or heart failure

or amyl nitrite also known as “poppers”, nicorandil or sodium nitroprusside), as the combination may lead to a dangerous fall in your blood pressure;

- take riociguat or other medicines of a group called guanylate cyclase stimulators. This medicine 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 due to blood clots);
- take ritonavir for the treatment of HIV infection;
- have been advised by your doctor to **avoid sexual activity** because of a problem with your heart or blood vessels, such as a recent stroke or a heart attack (within the last 6 months), unstable angina or severe cardiac failure;
- **have low blood pressure** (which can cause symptoms such as tiredness, dizziness, lightheadedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision) or high blood pressure that is not controlled;
- have ever had loss of vision because of damage to the optic nerve, such as non-arteritic anterior ischaemic optic neuropathy (NAION) or have an inherited eye disease (such as *retinitis pigmentosa*);
- have a severe liver problem;
- have any disease or deformity of your penis (such as Peyronie’s Disease);
- are a woman;
- 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 using Sildenafil Tablets to ensure that your erection problems are not caused by another 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 Sildenafil Tablets if you” above). Talk to your doctor before taking Sildenafil Tablets 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 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 heart beat (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 Sildenafil Tablets 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), 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 in the penis and permanent loss of ability to have an erection.
- have a stomach ulcer, or bleeding disorder (such as haemophilia);
- have previously been diagnosed mild to moderate liver disease, or severe kidney problems. Sildenafil Tablets may not be suitable for you, you should consult your doctor before taking Sildenafil Tablets.
- If you experience any sudden visual defect you should stop taking Sildenafil Tablets and contact your doctor immediately. Cases of visual effects have been reported when using sildenafil.

Children and adolescents

Sildenafil Tablets should not be given to children or adolescents under the age of 18 years.

Other medicines and Sildenafil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Sildenafil Tablets or they may affect how well Sildenafil Tablets will work and this may result in side effects.

Do not use Sildenafil Tablets if you take:

NITRATE medicines: Do NOT take Sildenafil Tablets 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 Sildenafil Tablets.

- Riociguat: Do not take Sildenafil Tablets 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 taken together with Sildenafil Tablets.
- Medicines to treat HIV-infections: Ritonavir is a medicine used to treat HIV-infections. Do not take Sildenafil Tablets if you are taking ritonavir since this combination can lead to a dangerous fall in blood pressure.

Tell your pharmacist or doctor before using Sildenafil Tablets 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 Sildenafil Tablets in the body and may result in side effects. You should contact your doctor before taking Sildenafil Tablets if you are using these medicines.
- Heartburn treatment: The medicine to treat heartburn, cimetidine, increases the concentration of Sildenafil Tablets in the body and may result in side effects. You should contact your doctor before taking Sildenafil Tablets.
- Other treatments for erectile dysfunction: The safety and efficacy of combinations of Sildenafil Tablets 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).
- Medicines containing sacubitril/valsartan, used to treat heart failure: You should contact your doctor or pharmacist before taking Sildenafil Tablets.

Sildenafil Tablets with food, drink and alcohol

Sildenafil Tablets can be taken with or without food. When this medicine is taken after a high-fat meal, it may take a little longer to start working. Do not take Sildenafil Tablets with grapefruit or grapefruit juice, because this can affect how the medicine works.

Drinking excessive alcohol can temporarily reduce your ability to achieve an erection. To get a benefit from the medicine, you are advised not to drink large amounts of alcohol before sexual activity.

Pregnancy, breast-feeding and fertility

Sildenafil Tablets should not be used by women.

Driving and using machines

Sildenafil Tablets can cause dizziness and can affect your vision. Do not drive or use machines if you suffer from these side effects after taking this medicine.

Sildenafil Tablets contain lactose monohydrate

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

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

3. How to take Sildenafil Tablets

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

- take one tablet, as needed, approximately 1 hour before sexual activity;
- swallow the tablet whole with water;
- **Do not take more than one tablet a day**

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

This medicine will only help you get 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 Sildenafil Tablets takes to work varies from person to person, but it normally takes between half an hour and one hour to work. You may take it up to 4 hours before sexual activity.

Relax and be patient if Sildenafil Tablets 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 Tablets 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 Tablets, and are still not able to get and keep an erection.

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

If you take more Sildenafil Tablets 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 an increase in side effects and/or more severe side effects.

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. These side effects are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking Sildenafil Tablets 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.
- A **prolonged and sometimes painful erection lasting longer than 4 hours:** this **rarely** occurs (may affect up to 1 in 1,000 people)
- A **sudden decrease or loss of vision** - this occurs rarely
- **Serious skin reactions** such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Syndrome (TEN)- 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, indigestion, stuffy nose and dizziness,
- facial flushing, hot flush (a sudden feeling of heat in your upper body),
- colour tinge to vision, blurred vision, visual disturbance.

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

- vomiting, upper abdominal pain, acid reflux (including heartburn),
- skin rash, pain in the arms or legs, nosebleed, feeling hot, feeling tired (fatigue)
- 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 (typical signs are dizziness, fainting, blurred vision, nausea and tiredness),

- 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 can be experienced as runny nose, sneezing and stuffy nose),
- presence of blood in urine.

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

- fainting, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing,
- sudden unexpected death caused by loss of heart function (sudden cardiac arrest), stroke, heart attack, chest pains (angina), 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sildenafil Tablets

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

This medicine does not require any special storage conditions.

DO NOT use this medicine after the expiry date which is stated on the carton 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 Tablets contains

- The active substance is sildenafil. Each tablet contains 50mg 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, titanium dioxide (E171), lactose monohydrate, triacetin.

What Sildenafil Tablets look like and contents of the pack

Sildenafil 50mg film-coated tablets are white, oval shaped, biconvex, film coated tablets, plain on one side and debossed with “C1” on the other side.

The tablets are provided in blister packs containing 4 or 8 tablets in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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