175 mm

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Package Leaflet: Information for the user

Sildenafil 50 mg Film-Coated Tablets

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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- If you have taken Sildenafil 50 mg Film-Coated Tablets as directed and were NOT able to get or keep an erection hard enough for satisfactory sex, you should talk to your pharmacist or doctor.

What is in this leaflet?

1. What Sildenafil 50 mg Film-Coated Tablets are and what they are used for
2. What you need to know before you take Sildenafil 50 mg Film-Coated Tablets
3. How to take Sildenafil 50 mg Film-Coated Tablets
4. Possible side effects
5. How to store Sildenafil 50 mg Film-Coated Tablets
6. Contents of the pack and other information

1. What Sildenafil 50 mg Film-Coated Tablets are and what they are used for

Sildenafil 50 mg Film-Coated Tablets are 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 50 mg Film-Coated Tablets contain the active ingredient sildenafil. It 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 50 mg Film-Coated 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 50 mg Film-Coated Tablets

✕ **Do NOT take Sildenafil 50 mg Film-Coated Tablets if you:**
- **do not have an erection problem, as this medicine will not provide any benefit to you;**
- **take any 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 blood pressure;
- are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6);
- 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 heart attack or stroke (within the last 6 months), unstable angina or severe cardiac failure;
- 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 low blood pressure** (which can cause symptoms such as tiredness, dizziness, light-headedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision) or high blood pressure that is not controlled;
- 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
Sexual activity can put extra strain on your heart. If you have a heart problem or think you might have a heart problem you should tell your pharmacist.

It is important to have a check-up with your doctor as soon as possible within the first 6 months of using Sildenafil 50 mg Film-Coated Tablets to ensure that your erection problems are not caused by another serious health condition.

Even if you feel healthy, your erection problems may be linked to other serious health conditions. Erectile dysfunction may be an early sign of:
- heart and blood vessel problems
- diabetes
- high blood pressure
- high cholesterol

You should discuss your symptoms and these conditions with your doctor if you have not already done so.

! **Before taking Sildenafil 50 mg Film-Coated Tablets, to ensure this medicine is suitable for you and that you are fit enough to have sex, tell your doctor 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 one of the valves 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)
- have had surgery to improve blood flow to your heart, or you have high blood pressure which is now under control;
- have ever had an erection that lasted more than 4 hours even without any physical or psychological stimulation (called priapism); or have any condition which can cause priapism. Conditions which can cause priapism include sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow).
- take any other medicines listed in this leaflet. Please refer to section 2 'Other medicines and Sildenafil 50 mg Film-Coated Tablets';
- have a stomach ulcer or a bleeding disorder (such as haemophilia);
- have previously diagnosed mild to moderate liver disease, or severe kidney problems. Sildenafil 50 mg Film-Coated Tablets may not be suitable for you. Ask your pharmacist or doctor about a 25 mg tablet which may be more suitable for you.

Children and adolescents
This medicine should not be given to children or adolescents under the age of 18 years.

Other medicines and Sildenafil 50 mg Film-Coated Tablets
Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Sildenafil 50 mg Film-Coated Tablets or they may affect how well Sildenafil 50 mg Film-Coated Tablets will work.
- **NITRATE medicines: Do NOT take Sildenafil 50 mg Film-Coated Tablets if you are taking nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) or nitric oxide donors (such as amyl nitrite ("poppers"), nicorandil or sodium nitroprusside).** These are often used for the relief of chest pain (angina pectoris), or heart failure. Using Sildenafil 50 mg Film-Coated Tablets with any of these medicines may lead to a dangerous fall in blood pressure.
- Do not take Sildenafil 50 mg Film-Coated Tablets if you are taking a medicine called riociguat (or other medicines of a group called guanylate cyclase stimulators), 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).
- In addition, do not take Sildenafil 50 mg Film-Coated Tablets if you are taking a medicine called ritonavir, for the treatment of HIV infection.
- Medicines containing sacubitril/valsartan, used to treat heart failure.

! **Tell your pharmacist or doctor before using Sildenafil 50 mg Film-Coated Tablets if you are taking:**
- any other treatment for erectile dysfunction;
- alpha-blockers such as alfuzosin, doxazosin or tamsulosin, which are medicines used to treat urinary problems due to an enlarged prostate (benign prostatic hyperplasia) or occasionally high blood pressure, as Sildenafil 50 mg Film-Coated Tablets may not be suitable for you;
- medicines that may affect the way Sildenafil 50 mg Film-Coated Tablets works such as:
  - protease inhibitors (saquinavir) to treat HIV infections;
  - the heartburn treatment cimetidine;
  - medicines to treat fungal infections called itraconazole or ketoconazole, and an antibiotic called erythromycin.

Sildenafil 50 mg Film-Coated Tablets may not be suitable for you. Ask your pharmacist or doctor about a 25 mg tablet which may be more suitable for you.

Sildenafil 50 mg Film-Coated Tablets with food and drink
Sildenafil 50 mg Film-Coated 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 50 mg Film-Coated Tablets with grapefruit or grapefruit juice, because this can affect how the medicine works.

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

Pregnancy, breastfeeding and fertility
This medicine should not be used by women.

Driving and using machines
Sildenafil 50 mg Film-Coated 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.

Important information about some of the ingredients of Sildenafil 50 mg Film-Coated Tablets
If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, speak to your pharmacist or doctor before taking this medicine.

Other important information
You can improve your erectile function by making lifestyle changes; these include exercising regularly, reducing stress, giving up smoking and avoiding excessive alcohol use. If you are feeling depressed or anxious, talk to your pharmacist or doctor, who will be able to provide you with further advice.

3. How to take Sildenafil 50 mg Film-Coated Tablets

Always take Sildenafil 50 mg Film-Coated Tablets exactly as described in this leaflet or as your pharmacist or doctor has told you. Check with your pharmacist or doctor 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 will not get an erection just by taking Sildenafil 50 mg Film-Coated Tablets. 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 this medicine takes to work varies from person to person, but it normally takes between 30 to 60 minutes to work. You may take it up to 4 hours before sexual activity.

Remember to relax and be patient. There is no rush. If you are not successful the first time, try to have sex again, but remember you can **only take 1 tablet a day**. For most men, Sildenafil 50 mg Film-Coated 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 are able to achieve an erection. If you feel the effect of Sildenafil 50 mg Film-Coated Tablets is too strong or too weak, talk to your pharmacist or doctor.

Talk to your doctor if you have taken Sildenafil 50 mg Film-Coated Tablets as directed and are still not able to get and keep an erection.

! **If you take more Sildenafil 50 mg Film-Coated 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 their severity.

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

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.

! **STOP TAKING Sildenafil 50 mg Film-Coated Tablets and seek medical attention IMMEDIATELY if you experience any of the following SERIOUS side effects:**
- **Chest pains:** this occurs uncommonly. If this occurs before, during or after intercourse get in a semi-sitting position and try to relax. Do NOT use nitrates to treat your chest pain.
- **A persistent and sometimes painful erection lasting longer than 4 hours:** this rarely occurs.
- **A sudden decrease or loss of vision:** this occurs rarely.
- **An allergic reaction:** this occurs uncommonly. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- **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 that have been reported

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

Common (may affect up to 1 in 10 people):
- nausea, indigestion, stuffy nose, dizziness
- facial flushing, hot flush (symptoms include 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, gastro-oesophageal reflux disease (also known as acid reflux with symptoms including heartburn)
- skin rash, pain in the arms or legs, nosebleed, feeling hot, feeling tired
- 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 (symptoms include 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 (symptoms include 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
- 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

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 this medicine.

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 50 mg Film-Coated Tablets

Keep out of the sight and reach of children.
This medicine requires no special storage precautions.
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 protect the environment.

6. Contents of the pack and other information

What Sildenafil 50 mg Film-Coated Tablets contains
- The active substance is sildenafil. Each tablet contains 50 mg of sildenafil (as citrate).
- The other ingredients are:
  Tablet core: Cellulose microcrystalline, Calcium hydrogen phosphate anhydrous, Croscarmellose sodium, Hypromellose (E464), Magnesium stearate
  Film coat: Hypromellose (E464), Titanium dioxide (E171), Lactose monohydrate, Triacetin, Indigo carmine aluminium lake (E132)

What Sildenafil 50 mg Film-Coated Tablets look like and contents of the pack
Sildenafil 50 mg Film-Coated Tablets are blue, almond shaped, biconvex, film-coated tablets, debossed with '50' on one side and plain on the other side.
The tablets are provided in blister packs containing 2, 4 or 8 tablets within a carton. Some pack sizes may not be marketed.

Marketing Authorisation Holder:
Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Distributed by:
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Manufacturer:
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