

Sidena 50 mg Tablets (sildenafil)

Pharmacy Consultation Guide

The following has been created as a useful aide-memoire to help determine whether your patient is suitable for Sidena 50 mg tablets, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide when and how to use it. The Essential Information for the Supply of Sidena provides additional background information in relation to the supply of this product.

If the patient has previously been supplied with Sidena, he should be asked if anything has changed with respect to his health status or medicines usage. There is no need to repeat the questions below prior to resupply in that case. Remind the patient to make an appointment with his doctor as soon as he can within the first 6 months of starting to use Sidena, to ensure that their erection problems are not caused by any serious health condition. If any factors have changed, Sections 2–4 should be reviewed again. The repeat supply tear-off slip (below) can also be given to the man.

1. Who is Sidena for?

Sidena is only intended for men 18 years and older who are experiencing erectile dysfunction (ED) (i.e., difficulty in getting and/or maintaining an erection satisfactory for sexual performance).

This product must not be supplied to men who do not have ED.

It is important to confirm if the man is already receiving treatment for the condition. Men currently prescribed 50 mg of sildenafil can be supplied this product if they meet the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If the man is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

2. Check patient's cardiovascular (CV) health

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor. If you have any reason to consider, based on physical status, the patient should not be using this product, refer to the doctor.

- ☐ Y ☐ N
- Has your doctor advised that you are not fit enough for any physical and/or sexual activity?
- ☐ Y ☐ N
- Do you feel very breathless or experience chest pain with light or moderate physical activity, such as walking briskly for 20 minutes or climbing two flights of stairs?
- ☐ Y ☐ N
- Have you had a heart attack or stroke within the last 6 months?
- ☐ Y ☐ N
- Do you have any other heart problems or are you under a doctor's care for any of the following:
- Low blood pressure or uncontrolled high blood pressure
 - Unstable angina (chest pain), irregular heartbeat or palpitations (arrhythmia)
 - A problem with one of the valves in your heart (valvular heart disease)
 - A problem where the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy)
 - Heart problems causing blood flow issues (e.g. left ventricular outflow obstruction, aortic narrowing) or severe cardiac failure

3. Check concomitant medication use

Please check what other medicines the patient is taking.

If the patient answers **YES** to any of the following or if there is uncertainty around the patient's current medications: **do not supply the product** and refer to the doctor.

- ☐ Y ☐ N
- Are you taking nitrates (nicorandil or other nitric oxide donors e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?
- ☐ Y ☐ N
- Are you using drugs called 'poppers' for recreational purposes (e.g. amyl nitrite)?
- ☐ Y ☐ N
- Are you taking riociguat or other guanylate cyclase stimulators for lung problems?
- ☐ Y ☐ N
- Are you taking ritonavir (for HIV infection)?
- ☐ Y ☐ N
- Are you taking any CYP3A4 inhibitors, e.g. saquinavir (to treat HIV infection), cimetidine (a heartburn treatment), itraconazole or ketoconazole (to treat fungal infections), erythromycin or rifampicin (antibiotics) or diltiazem (for high blood pressure)?
- ☐ Y ☐ N
- Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin, which are medicines to treat urinary problems due to enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

4. Check concomitant conditions

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor.

- ☐ Y ☐ N
- Do you have Peyronie's disease or any other deformation of the penis?
- ☐ Y ☐ N
- 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)?
- ☐ Y ☐ N
- Do you have previously diagnosed hepatic (liver) disease (including cirrhosis of the liver) or severe renal (kidney) impairment?
- ☐ Y ☐ N
- Do you have any of the following: sickle cell anaemia, multiple myeloma or leukaemia?
- ☐ Y ☐ N
- Do you have any bleeding issues (e.g. haemophilia) or have active stomach ulcers?

Additional advice

You should consider possible causes of erectile dysfunction, such as undiagnosed depression, anxiety, excessive alcohol use and taking certain medicines. Examples of classes of medicines that cause ED include diuretics, anti-hypertensives, corticosteroids, anticonvulsants and recreational drugs. Whilst it may be appropriate to supply the product, you should provide lifestyle advice and recommend a follow-up with a doctor.



Dear Doctor,

Please can you review this patient in relation to erectile dysfunction. We had a discussion in this pharmacy, but he was not suitable for supply of Sidena due to his [delete as appropriate] cardiovascular health/interacting medicines/other condition:

PHARMACY
STAMP

Pharmacist signature: Date:

Please keep this slip and present to the Pharmacist when you next wish to purchase Sidena.

Before resupplying your Pharmacist will need to assess you to ensure that there have been no changes in your health or medications since the last time you received the product.

PHARMACY
STAMP

Pharmacist signature: Date:

Points for counselling and other information

Please follow these points to ensure that your patient is counselled appropriately whether they are supplied the product or not.

Advice for men who have not been supplied Sildenafil

Men who have not been supplied Sildenafil because of their cardiovascular health, interacting medicines or another concern must be told to see their GP as soon as they can within 6 months. The tear-off slip (below) can be filled in and given to the man to facilitate his discussion with the doctor.

Advice for men who have been supplied Sildenafil

Men should be advised:

- They should schedule a health check-up with their doctor as soon as possible within the first 6 months of starting to use Sildenafil to ensure that their erection problems are not caused by any serious health condition
- Sildenafil is only intended for men 18 years and older who have erectile dysfunction (ED). Men who do not have ED will not benefit from using this product
- Take one tablet approximately 1 hour before planning to have sexual intercourse. Sildenafil can start to work within 30 minutes
- Take with or without food, but Sildenafil may take longer to work after a high-fat meal
- Do not take with grapefruit or grapefruit juice, as it may affect the way the medicine works
- The maximum recommended dosing frequency is one 50 mg tablet per day
- They may need to take Sildenafil a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If, after several attempts on different dosing occasions, patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor.
- Medicines containing any nitrates (e.g. glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, amyl nitrite also known as 'poppers'), or nitric oxide donors (e.g. sodium nitroprusside or nicorandil), must NOT be used at the same time as Sildenafil as this combination may lead to a dangerous fall in blood pressure
- Men should tell their doctor that they have started taking Sildenafil, especially if they are started on any new medicines
- Remind patients about common side effects. These include: headache, flushing, dyspepsia, nasal congestion, dizziness, nausea, visual disturbance, cyanopsia (blue-tinted vision) and blurred vision.

Note: If any of these become a concern, advise the patient to talk with a pharmacist or doctor.

Men should be advised to STOP TAKING Sildenafil and seek medical attention IMMEDIATELY if they experience any of the following SERIOUS side effects. Side effects can be reported by patients or pharmacists via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

- Chest pains: If this occurs before, during or after intercourse, they should get into a semi-sitting position and try to relax. Nitrates must NOT be used to treat chest pains
- A persistent and sometimes painful erection lasting longer than 4 hours
- A sudden decrease or loss of vision
- An allergic reaction. 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). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever
- Seizures or fits

Follow up advice for all men

- ED can be associated with a number of contributing conditions, e.g. hypertension, diabetes mellitus, hypercholesterolaemia or cardiovascular disease. As a result, all men with ED should be advised to consult their doctor within 6 months for a clinical review of potential underlying conditions and risk factors associated with ED
- Provide appropriate advice on lifestyle factors and general healthy living, including:
 - Losing weight
 - Giving up smoking
 - Cutting back on alcohol/recreational drugs
 - Exercising regularly
 - Reducing stress
- You may also want to check if the man is buying products from unregulated sources. It is important to explain these products are not tested for their safety or effectiveness, may not contain the ingredients listed within them and are therefore potentially dangerous, unlike product sourced from a pharmacy and medicines obtained via prescription from the doctor

Your Pharmacist has supplied you with Sildenafil today for your personal use.

Please make an appointment to see your GP as soon as you can within 6 months of the date of first receiving Sildenafil (see date on reverse) to check for underlying medical problems that can sometimes be associated with erectile dysfunction.

You have not been provided with Sildenafil for ED today as it may not be suitable for you to take without consulting your doctor. You should go to see your doctor to discuss other suitable options.

Please make an appointment to see your GP as soon as you can within the next 6 months and present this slip.