

Sildenafil 50mg Film-coated Tablets Pharmacy Checklist

The checklist can be used to help determine whether your patient is suitable for Sildenafil 50mg or whether he should be seen by a doctor for further advice. The Pharmacy Training Guide provides additional background information in relation to the supply of this product.

If the patient has previously been supplied with Sildenafil 50mg, he should be asked if anything has changed with respect to his health status or medicines usage. If there are no changes, there is no need to repeat this checklist prior to supply. Remind him to follow up with his doctor within the first 6 months of use. If any factors have changed, sections 2 - 4 of the checklist should be reviewed again.

1. Who is Sildenafil 50mg for?

Sildenafil 50mg is only intended for use by men over 18 years of age 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 an erection problem.

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 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;
- uncontrolled high blood pressure, or low blood pressure
 - unstable angina (chest pain) irregular heart beat 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 man is taking.

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

- Y N Are you taking nitrates for chest pain?
- Y N Are you using drugs called "poppers" for recreational purposes (e.g. amyl nitrite)?
- Y N Are you taking riociguat for lung problems?
- Y N Are you taking ritonavir for HIV infection?
- Y N Are you taking any CYP3A4 inhibitors (e.g. erythromycin, saquinavir, cimetidine, diltiazem, fluconazole.)?
- Y N Are you taking any Alpha-blockers (e.g. doxazosin, tamsulosin)?

4. Check concomitant conditions

Men answering **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 galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption?
- 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/or recommend a follow up with a doctor.

Points for counselling and other information

Having ascertained that your patient is suitable for Sildenafil 50mg, this information will help ensure the product is used optimally. Please refer patients to the in-pack patient information leaflet.

Using Sildenafil 50mg

- The recommended dose is one 50 mg tablet taken as needed with water, approximately one hour before sexual activity. Avoid taking with a heavy meal.
- The maximum recommended dosing frequency is once per day. If Sildenafil 50mg is taken with food, the onset of activity may be delayed compared to the fasted state.
- Men should be advised that they may need to take Sildenafil 50mg 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.
- Remind patients that Sildenafil 50mg is only intended for men over 18 who have ED. Men who do not have ED will not benefit from using this product.
- Remind patients about common side effects. These include headache, flushing, dyspepsia, nasal congestion, dizziness, nausea, visual disturbance, cyanopsia (blue tinted vision) and blurred vision.
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 50mg and seek medical attention IMMEDIATELY if they experience any of the following SERIOUS side effects

- Chest pains: 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
- 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

- Erectile dysfunction (ED) can be associated with a number of contributing conditions, e.g. hypertension, diabetes mellitus, hypercholesterolemia 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
 - 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 and 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.

Advice for Men who have not been given the product

Most men who are not suitable to be given this product should go to their doctor for a review as their erectile dysfunction might be caused by another condition such as high blood pressure or heart disease. You can provide these men with a record of the discussion to take to their doctor.