

What are sildenafil tablets?

Sildenafil tablets are a prescription medicine used to treat erectile dysfunction (ED). You will not get an erection just by taking this medicine. Sildenafil tablets help a man with erectile dysfunction get and keep an erection only when he is sexually excited (stimulated).

Sildenafil tablets are not for use in women or children. It is not known if sildenafil tablets are safe and effective in women or children under 18 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about sildenafil tablets?

Sildenafil tablets can cause your blood pressure to drop suddenly to an unsafe level if they are taken with certain other medicines. Do not take sildenafil tablets if you take any other medicines called “nitrates.” Nitrates are used to treat chest pain (angina). A sudden drop in blood pressure can cause you to feel dizzy, faint, or have a heart attack or stroke.

Do not take sildenafil tablets if you take medicines called guanylate cyclase stimulators which include:

- Riociguat (Adempas[®]) a medicine that treats pulmonary arterial hypertension and chronic-thromboembolic pulmonary hypertension.

Tell all your healthcare providers that you take sildenafil tablets. If you need emergency medical care for a heart problem, it will be important for your healthcare provider to know when you last took sildenafil tablets.

Stop sexual activity and get medical help right away if you get symptoms such as chest pain, dizziness, or nausea during sex. Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease. Ask your doctor if your heart is healthy enough to handle the extra strain of having sex.

Sildenafil tablets do not protect you or your partner from getting sexually transmitted diseases, including HIV—the virus that causes AIDS.

Who should not take sildenafil tablets?

Do not take sildenafil tablets if you:

- take medicines called nitrates (such as nitroglycerin)
- use street drugs called “poppers” such as amyl nitrate or amyl nitrite, and butyl nitrate
- take any medicines called guanylate cyclase stimulators such as riociguat (Adempas)
- are allergic to sildenafil, as contained in sildenafil tablets and REVATIO[®], or any of the ingredients in sildenafil tablets. See the end of the Patient Information leaflet for a complete list of ingredients in sildenafil tablets.

What should I tell my healthcare provider before taking sildenafil tablets?

Before you take sildenafil tablets, tell your healthcare provider if you:

- have or have had heart problems such as a heart attack, irregular heartbeat, angina, chest pain, narrowing of the aortic valve or heart failure
- have had heart surgery within the last 6 months
- have pulmonary hypertension
- have had a stroke

- have low blood pressure, or high blood pressure that is not controlled
- have a deformed penis shape
- have had an erection that lasted for more than 4 hours
- have problems with your blood cells such as sickle cell anemia, multiple myeloma, or leukemia
- have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- have ever had severe vision loss, including an eye problem called non-arteritic anterior ischemic optic neuropathy (NAION)
- have bleeding problems
- have or have had stomach ulcers
- have liver problems
- have kidney problems or are having kidney dialysis
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Sildenafil tablets may affect the way other medicines work, and other medicines may affect the way sildenafil tablets work causing side effects. Especially tell your healthcare provider if you take any of the following:

- medicines called nitrates (see “**What is the most important information I should know about sildenafil tablets?**”)
- medicines called guanylate cyclase stimulators, such as riociguat (Adempas)
- medicines called alpha blockers such as Hytrin[®] (terazosin HCl), Flomax[®] (tamsulosin HCl), Cardura[®] (doxazosin mesylate), Minipress[®] (prazosin HCl), Uroxatral[®] (alfuzosin HCl), Jalyn[®] (dutasteride and tamsulosin HCl), or Rapaflo[®] (silodosin). Alpha-blockers are sometimes prescribed for prostate problems or high blood pressure. In some patients, the use of sildenafil tablets with alpha-blockers can lead to a drop in blood pressure or to fainting.
- medicines called HIV protease inhibitors, such as ritonavir (Norvir[®]), indinavir sulfate (Crixivan[®]), saquinavir (Fortovase[®] or Invirase[®]) or atazanavir sulfate (Reyataz[®])
- some types of oral antifungal medicines, such as ketoconazole (Nizoral[®]), and itraconazole (Sporanox[®])
- some types of antibiotics, such as clarithromycin (Biaxin[®]), telithromycin (Ketek[®]), or erythromycin
- other medicines that treat high blood pressure
- other medicines or treatments for ED
- sildenafil tablets contain sildenafil, which is the same medicine found in another drug called REVATIO. REVATIO is used to treat a rare disease called pulmonary arterial hypertension (PAH). Sildenafil tablets should not be used with REVATIO or with other PAH treatments containing sildenafil or any other PDE5 inhibitors (such as Adcirca[®] [tadalafil]).

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of sildenafil tablets?

Sildenafil tablets can cause serious side effects. Rarely reported side effects include:

- **an erection that will not go away (priapism).** If you have an erection that lasts more than 4 hours, get medical help right away. If it is not treated right away, priapism can permanently damage your penis.
- **sudden vision loss in one or both eyes.** Sudden vision loss in one or both eyes can be a sign of a serious eye problem called non-arteritic anterior ischemic optic neuropathy (NAION). It is uncertain whether PDE5 inhibitors directly cause the vision loss. Stop taking sildenafil tablets and call your healthcare provider right away if you have sudden vision loss in one or both eyes.
- **sudden hearing decrease or hearing loss.** Some people may also have ringing in their ears (tinnitus) or dizziness. If you have these symptoms, stop taking sildenafil tablets and contact a doctor right away.

The most common side effects of sildenafil tablets are: headache; flushing; upset stomach; abnormal vision, such as changes in color vision (such as having a blue color tinge) and blurred vision; stuffy or runny nose; back pain; muscle pain; nausea; dizziness; and rash.

In addition, heart attack, stroke, irregular heartbeats and death have happened rarely in men taking sildenafil tablets. Most, but not all, of these men had heart problems before taking sildenafil tablets. It is not known if sildenafil tablets caused these problems.

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of sildenafil tablets. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the Patient Information in the accompanying full Prescribing Information.