

PATIENT INFORMATION

Sildenafil (sil den' a fil) Tablets

Read this Patient Information before you start taking sildenafil tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about sildenafil tablets, ask your doctor or pharmacist.

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

Never take sildenafil tablets with any nitrate or guanylate cyclase stimulator medicines. Your blood pressure could drop quickly to an unsafe level.

Nitrate medicines include:

- Medicines that treat chest pain (angina)
- Nitroglycerin in any form including tablets, patches, sprays, and ointments
- Isosorbide mononitrate or dinitrate
- Street drugs called “poppers” (amyl nitrate or nitrite)

Guanylate cyclase stimulators include:

- Riociguat (Adempas)

Ask your doctor or pharmacist if you are not sure if you are taking a nitrate or a guanylate cyclase stimulator medicine.

What are sildenafil tablets?

Sildenafil tablet is a prescription medicine used in adults to treat pulmonary arterial hypertension (PAH). With PAH, the blood pressure in your lungs is too high. Your heart has to work hard to pump blood into your lungs.

Sildenafil tablet improves the ability to exercise and can slow down worsening changes in your physical condition.

- Sildenafil tablets is not for use in children
- Adding sildenafil tablets to another medication used to treat PAH, bosentan (Tracleer®), does not result in improvement in your ability to exercise.

Sildenafil tablets contains the same medicine as VIAGRA® (sildenafil), which is used to treat erectile dysfunction (impotence). Do not take sildenafil tablets with VIAGRA or other PDE-5 inhibitors.

Who should not take sildenafil tablets?

Do not take sildenafil tablets if you:

- take nitrate medicines. See “**What is the most important information I should know about sildenafil tablets?**”
- take guanylate cyclase stimulator medicines. See “**What is the most important information I should know about sildenafil tablets?**”
- are allergic to sildenafil or any other ingredient in sildenafil tablets. See “**What are the ingredients in sildenafil tablets?**” at the end of this leaflet.

What should I tell my doctor before taking sildenafil tablets?

Tell your doctor about all of your medical conditions, including if you

- have heart problems such as angina (chest pain), heart failure, irregular heartbeats, or have had a heart attack
- have a disease called pulmonary veno-occlusive disease (PVOD)
- have high or low blood pressure or blood circulation problems
- have an eye problem called retinitis pigmentosa
- have or had loss of sight in one or both eyes
- have any problem with the shape of your penis or Peyronie’s disease
- have any blood cell problems such sickle cell anemia
- have a stomach ulcer or any bleeding problems
- are pregnant or planning to become pregnant. It is not known if sildenafil tablets could harm your unborn baby.
- are breastfeeding. It is not known if sildenafil passes into your breast milk or if it could harm your baby.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. Sildenafil tablets and certain other medicines can cause side effects if you take them together. The doses of some of your medicines may need to be adjusted while you take sildenafil tablets.

Especially tell your doctor if you take

- Nitrate medicines. See “**What is the most important information I should know about sildenafil tablets?**”
- Riociguat (Adempas). See “**What is the most important information I should know about sildenafil tablets?**”
- Ritonavir (Norvir®) or other medicines used to treat HIV infection
- Ketoconazole (Nizoral®)
- Itraconazole (Sporanox)
- High blood pressure medicine

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take sildenafil tablets?

- Take sildenafil tablets exactly as your doctor tells you.

Sildenafil may be prescribed to you as

- Sildenafil tablets
- Take sildenafil tablets 3 times a day about 4 to 6 hours apart
- Take sildenafil tablets at the same times every day.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, skip the missed dose, and take your next dose at the regular time.
- Do not take more than one dose of sildenafil tablets at a time.
- Do not change your dose or stop taking sildenafil tablets on your own. Talk to your doctor first.
- **If you take too much sildenafil tablets, call your doctor or go to the nearest hospital emergency room.**

What are the possible side effects of sildenafil tablets?

- **low blood pressure.** Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy.
- **more shortness of breath than usual.** Tell your doctor if you get more short of breath after you start sildenafil tablets. More shortness of breath than usual may be due to your underlying medical condition.
- **decreased eyesight or loss of sight in one or both eyes (NAION).** If you notice a sudden decrease or loss of eyesight, talk to your doctor right away.
- **sudden decrease or loss of hearing.** If you notice a sudden decrease or loss of hearing, talk to your doctor right away. It is not possible to determine whether these events are related directly to this class of oral medicines, including sildenafil tablets, or to other diseases or medicines, to other factors, or to a combination of factors.
- **heart attack, stroke, irregular heartbeats, and death.** Most of these happened in men who already had heart problems.
- **erections that last several hours.** 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.

The most common side effects with sildenafil tablets include:

Nosebleed, headache, upset stomach, getting red or hot in the face (flushing), trouble sleeping, as well as fever, erection increased, respiratory infection, nausea, vomiting, bronchitis, pharyngitis, runny nose, and pneumonia in children.

Tell your doctor if you have any side effect that bothers you or doesn't go away.

These are not all the possible side effects of sildenafil tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sildenafil tablets?

- Store sildenafil tablets at room temperature, between 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- **Keep sildenafil tablets and all medicines away from children.**

General information about sildenafil tablets

Medicines are sometimes prescribed for purposes that are not in the patient leaflet. Do not use sildenafil tablets for a condition for which it was not prescribed. Do not give sildenafil tablets to other people, even if they have the same symptoms you have. It could harm them.

This patient leaflet summarizes the most important information about sildenafil tablets. If you would like more information about sildenafil tablets talk with your doctor. You can ask your doctor or pharmacist for information about sildenafil tablets that is written for health professionals.

What are the ingredients in sildenafil tablets?

Active ingredients: sildenafil citrate, USP

Inactive ingredients: croscarmellose sodium, dibasic calcium phosphate anhydrous, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide and triacetin

This Patient Information has been approved by the U.S. Food and Drug Administration



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