

PATIENT INFORMATION

Sildenafil (Sil den' a fil) for oral suspension

What is the most important information I should know about Sildenafil for oral suspension?

Never take Sildenafil for oral suspension with any nitrate or guanylate cyclase stimulator medicines.

- Your blood pressure could drop quickly to an unsafe level.

Nitrates 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, butyl nitrate or nitrite)

Guanylate cyclase stimulators include:

- Riociguat, a medicine that treats pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension.

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

See “**What are the possible side effects of Sildenafil for oral suspension?**” for more information about side effects.

What is Sildenafil for oral suspension?

Sildenafil for oral suspension is a prescription medicine used to treat pulmonary arterial hypertension (PAH). PAH is a type of high blood pressure in the arteries of your lungs. Sildenafil for oral suspension may be used in:

- adults to improve your ability to exercise and help slow down the worsening of your physical condition.

It is not known if Sildenafil for oral suspension is safe and effective in children younger than 1 year of age.

Do not take Sildenafil for oral suspension if you:

- take medicines called nitrates.
- take riociguat, a guanylate cyclase stimulator medicine.
- are allergic to sildenafil or any of the ingredients in Sildenafil for oral suspension. See the end of this leaflet for a complete list of ingredients in Sildenafil for oral suspension

Before taking Sildenafil for oral suspension, tell your healthcare provider about all of your medical conditions, including if you:

- have low blood pressure
- have heart problems
- have pulmonary veno-occlusive disease (PVOD)
- have bleeding problems or a stomach (peptic) ulcer. It is not known if Sildenafil for oral suspension is safe in people with bleeding problems or who have a stomach ulcer.
- have an eye problem called retinitis pigmentosa

- have ever had sudden loss of vision in one or both eyes, including an eye problem called non-arteritic anterior ischemic optic neuropathy (NAION)
- have ever had hearing problems such as ringing in the ears, dizziness, or loss of hearing
- have a deformed penis shape or Peyronie's disease
- have any blood cell problems such as sickle cell anemia
- are pregnant or plan to become pregnant. It is not known if Sildenafil will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Sildenafil passes into your breast milk. It is not known if it can harm your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with Sildenafil.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Sildenafil for oral suspension and certain other medicines may affect each other and can cause side effects.

Especially tell your healthcare provider if you take:

- nitrates or guanylate cyclase stimulators. See **“What is the most important information I should know about Sildenafil for oral suspension?”**
- medicines to treat high blood pressure
- medicines for erectile dysfunction (impotence). Sildenafil for oral suspension contains sildenafil, which is the same medicine found in another medicine called VIAGRA[®]. VIAGRA is used for the treatment of erectile dysfunction. **Do not** take VIAGRA or other PDE-5 inhibitors during treatment with Sildenafil for oral suspension.

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 your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take Sildenafil for oral suspension?

- Take or give Sildenafil for oral suspension exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose of Sildenafil for oral suspension as needed. Do not change your dose or stop taking Sildenafil for oral suspension without talking to your healthcare provider.
- Sildenafil for oral suspension may be prescribed to you as Sildenafil tablets or Sildenafil for oral suspension.
- Take your prescribed dose of Sildenafil tablets or oral suspension 3 times a day.
- **See the detailed Instructions for Use that comes with Sildenafil for oral suspension for information on how to take or give Sildenafil for oral suspension.** Sildenafil for oral suspension will be mixed for you by your pharmacist. Do not mix Sildenafil for oral suspension with other medicine or flavoring.
- If you take too much Sildenafil for oral suspension, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of Sildenafil for oral suspension?

Sildenafil for oral suspension may cause serious side effects, including:

- See “**What is the most important information I should know about Sildenafil for oral suspension?**”
- **Decreased blood pressure.** Sildenafil may cause low blood pressure that last for a short time. If you take medicines to treat high blood pressure, your healthcare provider should monitor your blood pressure during treatment with Sildenafil for oral suspension.
- **Decreased eyesight or permanent loss of vision in one or both eyes** can be a sign of non-arteritic anterior ischemic optic neuropathy (NAION). Most people who develop NAION have certain risk factors. You can ask your healthcare provider if you have questions about risk factors for NAION. If you notice a sudden decrease or loss of vision in one or both eyes during treatment with Sildenafil for oral suspension, contact your healthcare provider right away.
- **Sudden decrease or loss of hearing**, sometimes with ringing in the ears and dizziness. If you notice a sudden decrease or loss of hearing during treatment with Sildenafil for oral suspension, contact your healthcare provider right away.
- **In men, an erection that lasts for more than 4 hours (priapism).** If you have an erection, with or without pain, that lasts more than 4 hours, contact your healthcare provider or get emergency medical help right away. A painful erection that lasts more than 6 hours must be treated right away or you can have lasting damage to your penis, including the inability to have erections.

The most common side effects of Sildenafil for oral suspension in adults include:

- | | |
|---|-------------------------|
| • nosebleeds | • muscle aches and pain |
| • headache | • back pain |
| • upset stomach | • diarrhea |
| • getting red or hot in the face (flushing) | |
| • arm or leg pain | |

These are not all the possible side effects of Sildenafil for oral suspension.

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 for oral suspension?

- Store mixed (reconstituted) Sildenafil for oral suspension below 86°F (30°C) or in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not freeze mixed Sildenafil for oral suspension.
- Throw away (discard) any remaining Sildenafil for oral suspension 60 days after mixed by the pharmacist. See the “Discard after” date written on the bottle label.

Keep Sildenafil for oral suspension and all medicines out of the reach of children.

General information about the safe and effective use of Sildenafil for oral suspension.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Sildenafil for oral suspension for a condition for which it was not prescribed. Do not give Sildenafil for oral suspension to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about Sildenafil for oral suspension that is written for health professionals.

What are the ingredients in Sildenafil for oral suspension?

Sildenafil for oral suspension

Active ingredients: sildenafil citrate

Inactive ingredients: anhydrous citric acid, colloidal silicon dioxide, grape flavor, sodium benzoate, sorbitol, sucralose, titanium dioxide, trisodium citrate dihydrate and xanthan gum.

Pediatric use information is approved for Viatrix Specialty LLC's, REVATIO (sildenafil) tablets. However, due to Viatrix Specialty LLC's marketing exclusivity rights, this drug product is not labeled with that information.

Manufactured by:

Granules Pharmaceuticals Inc.,

Chantilly, VA 20151

For more information about Sildenafil for oral suspension, please contact Granules Pharmaceuticals Inc. at 1-877-770-3183.

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

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**Instructions for Use
Sildenafil (Sil den' a fil)
for oral suspension**

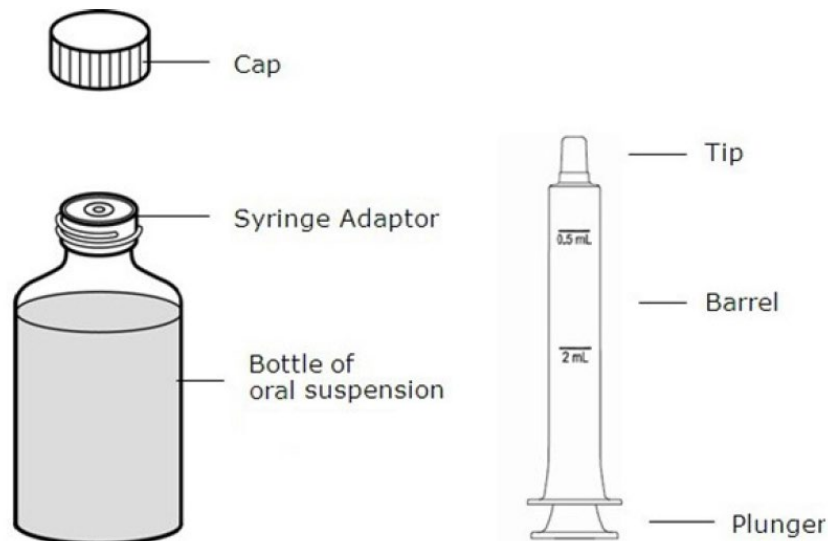
Read this Instructions for Use before you start taking Sildenafil for oral suspension and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Important information:

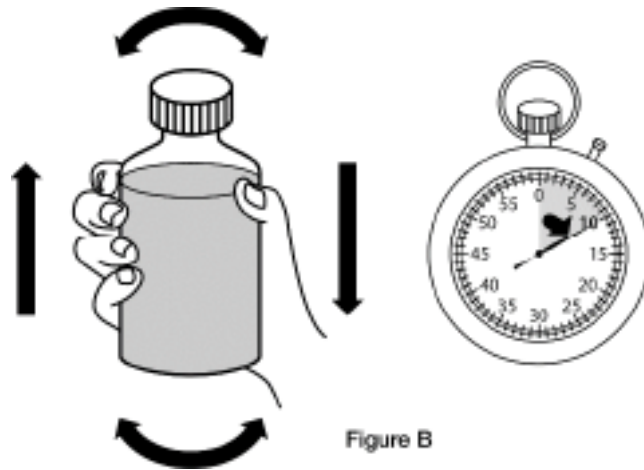
- Ask your healthcare provider or pharmacist to show you how to measure and take your prescribed dose of Sildenafil for oral suspension.
- Your pharmacist will mix (reconstitute) Sildenafil for oral suspension before it is given to you. **Do not** take or give Sildenafil for oral suspension and contact your pharmacist if the medicine in the bottle is still a powder.
- Always use the oral dosing syringe that comes with Sildenafil for oral suspension. If your carton does not come with an oral dosing syringe, contact your pharmacist.
- **Do not** take or give Sildenafil for oral suspension if the bottle adaptor is not in the bottle. If the bottle adaptor is not in the bottle, contact your pharmacist.
- Sildenafil for oral suspension should not be mixed with any other medicine or flavoring.

Supplies you will need to take or give a dose of Sildenafil for oral suspension (See Figure A):

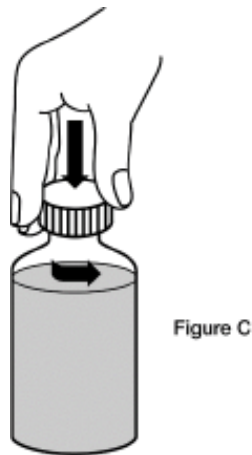
- 1 bottle of Sildenafil for oral suspension with pre-inserted bottle adaptor
- 1 oral dosing syringe (provided in the carton)



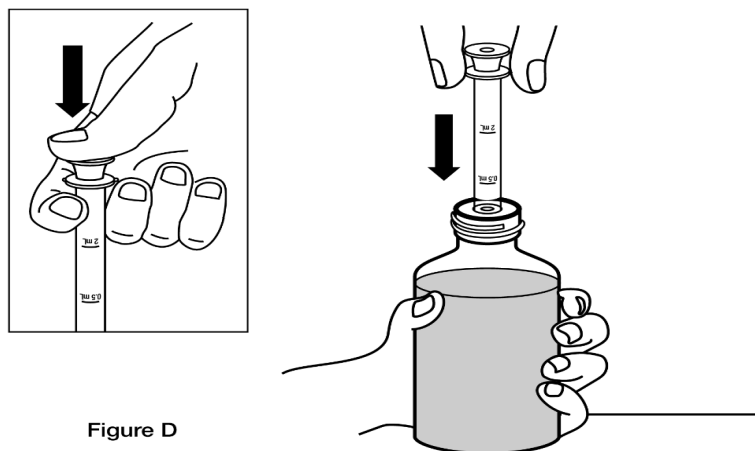
Step 1. Shake the bottle of Sildenafil for oral suspension for 10 seconds before each use. (See Figure B)



Step 2. Remove the cap. Open the bottle by pushing down on the cap and twisting it in the direction of the arrow (counter-clockwise). (See Figure C)



Step 3. Fully push down (depress) the plunger of the oral dosing syringe. Then insert the tip of the oral dosing syringe into the bottle adaptor while holding the bottle upright, on a flat surface. (See Figure D)



Step 4. Turn the bottle upside down while holding the oral dosing syringe in place. Slowly pull back the plunger of the oral dosing syringe until the bottom of the plunger is even with the mL marking on the syringe for your prescribed dose. (See Figure E)

If your dose of sildenafil for oral suspension is 1 mL (10 mg), measure 0.5 mL two times for a total of 1 mL of sildenafil for oral suspension.

If your dose of Sildenafil for oral suspension is more than 2 mL (20 mg), you will need to divide the dose. Follow the instructions given to you by your healthcare provider or pharmacist about how to prepare the divided dose.

If you see air bubbles in the oral dosing syringe, slowly push the plunger all the way up so that Sildenafil for oral suspension flows back into the bottle and repeat Step 4.

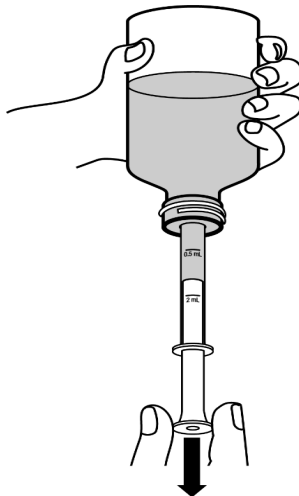


Figure E

Step 5. Turn the bottle back upright with the oral dosing syringe still in place. Place the bottle on a flat surface. Remove the oral dosing syringe from the bottle adaptor by pulling straight up on the barrel of the oral dosing syringe. (See Figure F) **Do not press on the plunger of the oral dosing syringe at this time.**

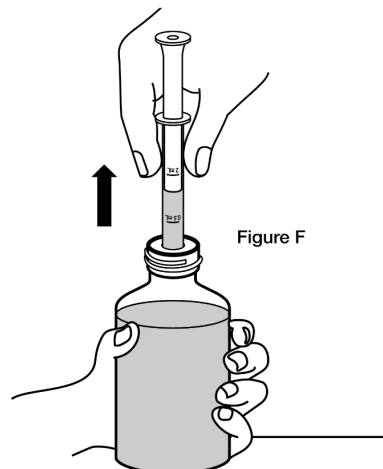


Figure F

Step 6. Put the tip of the oral dosing syringe into your mouth and point it towards the inside of the cheek. Slowly push the plunger of the oral dosing syringe all the way down to give the entire dose. Do not squirt the medicine out quickly. (See Figure G)

If you are giving Sildenafil for oral suspension, make sure they are in an upright position before giving the medicine.

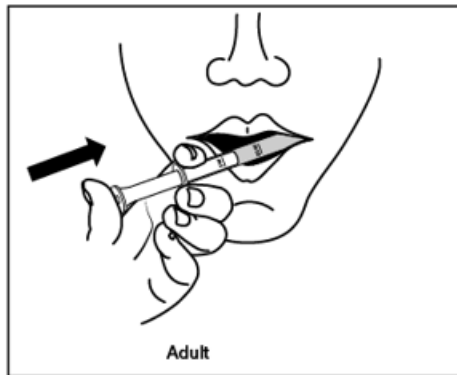


Figure G

Step 7. Replace the cap on the bottle, leaving the bottle adaptor in place. Turn the cap in the direction of the arrow (clockwise) to close the bottle. (See Figure H)

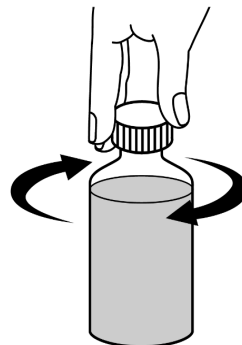


Figure H

Step 8. Wash the oral dosing syringe after each use. Pull the plunger out of the barrel and rinse both parts with water. (See Figure I)

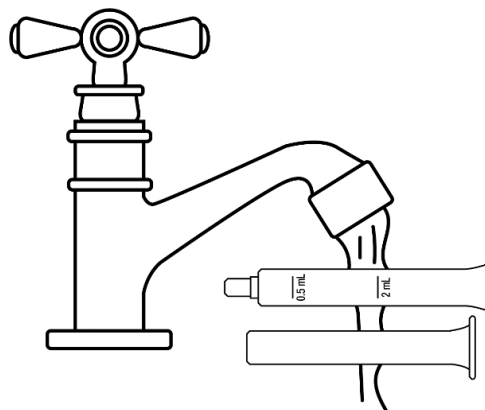


Figure I

Step 9. Dry all parts with a clean paper towel. Push the plunger back into the barrel. Store the oral dosing syringe with the Sildenafil for oral suspension bottle.

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