

Before taking tadalafil:

- Tell your doctor and pharmacist if you are allergic to tadalafil, any other medications, or any of the ingredients in tadalafil tablets. Ask your pharmacist for a list of the ingredients.
- Tell your doctor if you are taking or have recently taken riociguat (Adempas) or nitrates such as isosorbide dinitrate (Isordil), isosorbide mononitrate (Monoket), and nitroglycerin (Minitran, Nitro-Dur, Nitromist, Nitrostat, others). Nitrates come as tablets, sublingual (under the tongue) tablets, sprays, patches, pastes, and ointments. Ask your doctor if you are not sure whether any of your medications contain nitrates. Your doctor will probably tell you not to take tadalafil if you are taking nitrates.
- Tell your doctor if you are taking street drugs containing nitrates ('poppers') such as amyl nitrate, butyl nitrate, or nitrite while taking tadalafil. Your doctor will probably tell you not to take tadalafil if you are taking street drugs containing nitrates.
- Tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: alpha blockers such as alfuzosin (Uroxatral), doxazosin (Cardura), dutasteride (Avodart, in Jalyn), prazosin (Minipress), silodosin (Rapaflo), tamsulosin (Flomax, in Jalyn), and terazosin; amiodarone (Cordarone, Pacerone); certain antifungals such as fluconazole (Diflucan), griseofulvin (Grifulvin, Gris-PEG), itraconazole (Onmel, Sporanox), ketoconazole (Extina, Ketozole, Nizoral, Xolegel), and voriconazole (Vfend); aprepitant (Emend); bosentan (Tracleer); carbamazepine (Carbatrol, Epitol, Tegretol, Teril, others); clarithromycin (Biaxin, in Prevpac); diltiazem (Cardizem, Cartia, Tiazac, others); efavirenz (Sustiva, in Atripla); erythromycin (E.E.S., E-Mycin, Erythrocin); HIV protease inhibitors including indinavir (Crixivan), nelfinavir (Viracept), and ritonavir (Norvir, in Kaletra), lovastatin (Altacor, in Advicor); medications for high blood pressure; nefazodone; nevirapine (Viramune); other medications or treatments for erectile dysfunction; other medications or treatments for PAH; phenobarbital; phenytoin (Dilantin, Phenytek); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); sertraline (Zoloft); telithromycin (Ketek); and verapamil (Calan, Covera, Verelan, in Tarka). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor what herbal products you are taking, especially St. John's wort.
- Tell your doctor if you smoke; if you have ever had an erection that lasted more than 4 hours; and if you have recently had diarrhea, vomiting, not been drinking enough fluids, or sweating a lot which may have caused dehydration (loss of a large amount of body fluids). Also tell your doctor if you have or have ever had pulmonary veno-occlusive disease (PVOD; blockage of veins in the lungs); any condition that affects the shape of the penis; diabetes; high cholesterol; high or low blood pressure; irregular heartbeat; a heart attack or heart failure; angina (chest pain); a stroke; ulcers in the stomach; a bleeding disorder; blood circulation problems; blood cell problems such as sickle cell anemia (a disease of the red blood cells), multiple myeloma (cancer of the plasma cells), or leukemia (cancer

of the white blood cells); or heart, kidney, or liver disease. Also tell your doctor if you or any of your family members have or have ever had an eye disease such as retinitis pigmentosa (an inherited eye condition that causes loss of vision) or if you have ever had sudden severe vision loss, especially if you were told that the vision loss was caused by a blockage of blood flow to the nerves that help you see.

- if you are a woman and you are taking tadalafil to treat PAH, tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking tadalafil, call your doctor.
- If you are having surgery, including dental surgery, tell the doctor or dentist that you are taking tadalafil.
- Talk to your doctor about the safe use of alcoholic beverages during your treatment with tadalafil. If you drink a large amount of alcohol (more than five glasses of wine or five shots of whiskey) while you are taking tadalafil you are more likely to experience certain side effects of tadalafil such as dizziness, headache, fast heartbeat, and low blood pressure.
- If you are taking tadalafil to treat erectile dysfunction, tell your doctor if you have ever been advised by a health care professional to avoid sexual activity for medical reasons or if you have ever experienced chest pain during sexual activity. Sexual activity may be a strain on your heart, especially if you have heart disease. If you experience chest pain, dizziness, or nausea during sexual activity, call your doctor immediately or get emergency medical treatment, and avoid sexual activity until your doctor tells you otherwise.
- Tell all your health care providers that you are taking tadalafil. If you ever need emergency medical treatment for a heart problem, the health care providers who treat you will need to know when you last took tadalafil.
- Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

What should I do if I forget a dose?

- If you are taking tadalafil for erectile dysfunction on a regular schedule, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose or more than one dose per day to make up for a missed one.

If you are taking tadalafil for PAH or BPH, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Tadalafil may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- Headache
- Indigestion or heartburn
- Nausea
- Diarrhea
- Flushing
- Pain in the stomach, back, muscles, arms, or legs
- Cough

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- Sudden decrease or loss of vision (see below for more information)
- Blurred vision
- Changes in color vision (seeing a blue tinge on objects or having difficulty telling the difference between blue and green)
- Sudden decrease or loss of hearing (see below for more information)
- Ringing in ears
- Erection that lasts longer than 4 hours
- Dizziness
- Chest pain
- Hives
- Rash
- Difficulty breathing or swallowing
- Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- Blistering or peeling of skin

Some patients experienced a sudden loss of some or all of their vision after they took tadalafil or other medications that are similar to tadalafil. The vision loss was permanent in some cases. It is not known if the vision loss was caused by the medication. If you experience a sudden loss of vision while you are taking tadalafil, call your doctor immediately or get emergency medical treatment. Do not take any more doses of tadalafil or similar medications such as sildenafil (Revatio, Viagra) or vardenafil (Levitra) until you talk to your doctor.

Some patients experienced a sudden decrease or loss of hearing after they took tadalafil or other medications that are similar to tadalafil. The hearing loss usually involved only one ear and did not always improve when the medication was stopped. It is not known if the hearing loss was caused by the medication. If you experience a sudden loss of hearing, sometimes with ringing in the ears or dizziness, while you are taking tadalafil, call your doctor immediately. Do not take any more doses of tadalafil or similar medications such as sildenafil (Revatio, Viagra) or vardenafil (Levitra) until you talk to your doctor.

Tadalafil may cause other side effects. Call your doctor if you have any unusual problems while taking this medication

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online <http://www.fda.gov/Safety/MedWatch> or by phone (1-800-332-1088).