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Tadalafil

pronounced as (tah da' la fil)

Why is this medication prescribed?

Tadalafil (Cialis) is used to treat erectile dysfunction (ED, impotence; inability to get or keep an erection), and the symptoms of benign prostatic hyperplasia (BPH; an enlarged prostate) which include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and urinary frequency and urgency in adult men. Tadalafil (Adcirca) is used to improve the ability to exercise in people with pulmonary arterial hypertension (PAH; high blood pressure in the vessels carrying blood to the lungs, causing shortness of breath, dizziness, and tiredness). Tadalafil is in a class of medications called phosphodiesterase (PDE) inhibitors. It works to treat erectile dysfunction by increasing blood flow to the penis during sexual stimulation. This increased blood flow can cause an erection. Tadalafil treats PAH by relaxing the blood vessels in the lungs to allow blood to flow more easily.

If you are taking tadalafil to treat erectile dysfunction, you should know that it does not cure erectile dysfunction or increase sexual desire. Tadalafil does not prevent pregnancy or the spread of sexually transmitted diseases such as human immunodeficiency virus (HIV).

How should this medicine be used?

Tadalafil comes as a tablet to take by mouth. It may be taken with or without food.

If you are taking tadalafil to treat erectile dysfunction, follow your doctor's directions and the guidelines in this paragraph. There are two different ways to take tadalafil, either daily or on an as needed basis. Talk to your doctor about which dosing schedule is right for you. Tadalafil is sometimes taken as needed, usually at least 30 minutes before sexual activity and not more often than once every 24 hours. Your doctor will help you decide the best time for you to take tadalafil before sexual activity. Tadalafil is also sometimes taken once a day every day without regard to timing of sexual activity. You may attempt sexual activity at any time between doses. If you are taking tadalafil on a regular schedule, take it at around the same time every day. If you have certain health conditions or are taking certain medications, your doctor may tell you to take tadalafil less often or may prescribe a lower dose to be taken once a day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take tadalafil exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking tadalafil to treat PAH or BPH, follow your doctor's directions and the guidelines in this paragraph. You should take tadalafil one time a day. Take all of the tablets for your daily dose at one time each day; do not divide the tablets to take as separate doses. Take tadalafil at around the same time every day. If you are already taking medication to treat BPH, your doctor may tell you to stop taking your other medication at least one day before starting treatment with tadalafil. Follow your doctor's directions carefully, and ask your doctor or pharmacist to explain any part you do not understand.

If you are taking tadalafil for erectile dysfunction, your doctor will probably start you on an average dose of tadalafil and increase or decrease your dose depending on your response to the medication. Tell your doctor if tadalafil is not working well or if you are experiencing side effects.

If you are taking tadalafil for PAH, you should know that tadalafil controls PAH but does not cure it. Continue to take tadalafil even if you feel well. Do not stop taking tadalafil without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

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.
- you should know that tadalafil is available under the brand names Adcirca and Cialis. You should only be treated with one of these products at a time.
- 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.

What special dietary instructions should I follow?

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.

What side effects can this medication cause?

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> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Adcirca[®]
- Cialis[®]
- Entadfi[®] (as a combination product containing Finasteride, Tadalafil)

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