

**Patient Information**

**Tadalafil (ta da' /fil) Tablets, USP**

Read this important information before you start taking Tadalafil Tablets and each time you get a refill. There may be new information. You may also find it helpful to share this information with your partner. This information does not take the place of talking with your healthcare provider. You and your healthcare provider should talk about Tadalafil Tablets when you start taking it and at regular checkups. If you do not understand the information, or have questions, talk with your healthcare provider or pharmacist.

**What Is the Most Important Information I Should Know About Tadalafil Tablets?**  
Tadalafil Tablets can increase blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines. You could get dizzy, faint, or have a heart attack or stroke. Never take Tadalafil Tablets with any nitrate or guanylate cyclase stimulator medicines.

Do not take Tadalafil Tablets if you take any medicines called "nitrates." Nitrates are commonly used to treat angina. Angina is a symptom of heart disease and can cause pain in your chest, jaw, or down your arm.

Medicines called nitrates include nitroglycerin that is found in tablets, sprays, ointments, pastes, or patches. Nitrates can also be found in other medicines such as isosorbide dinitrate or isosorbide mononitrate. Some recreational drugs called "poppers" also contain nitrates, such as amyl nitrite and butyl nitrite.

Do not take Tadalafil Tablets if you take medicines called guanylate cyclase stimulators which include: rosiglitazone (Avanpose™) a medicine that treats prediabetes and type 2 diabetes; or any medicine for chronic thromboembolic pulmonary hypertension.

Ask your healthcare provider or pharmacist if you are not sure if any of your medicines are nitrates or guanylate cyclase stimulators, such as rosiglitazone (Avanpose™) or any medicine for chronic thromboembolic pulmonary hypertension. Tell all of your healthcare providers that you take Tadalafil 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 Tadalafil Tablets.

After taking a single tablet, some of the active ingredient in Tadalafil Tablets remains in your body for more than 2 days. The active ingredient can remain longer if you have problems with your kidneys or liver, or you are taking certain other medications (see "Can Other Medicines Affect Tadalafil 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. Also see "What Are The Possible Side Effects Of Tadalafil Tablets?"

**What Are Tadalafil Tablets?**  
Tadalafil Tablets are a prescription medicine taken by mouth for the treatment of:

- erectile dysfunction (ED)
- men with symptoms of benign prostatic hyperplasia (BPH)
- men with both ED and BPH

**Tadalafil Tablets for the Treatment of ED**  
ED is a condition where the penis does not fill with enough blood to harden and expand when a man is sexually excited, or when he cannot keep an erection. A man who has trouble getting or keeping an erection should see his healthcare provider for help if the condition bothers him. Tadalafil Tablets help increase blood flow to the penis and may help men with ED get and keep an erection satisfactory for sexual activity. Once a man has completed sexual activity, blood flow to his penis decreases, and his erection goes away.

Some form of sexual stimulation is needed for an erection to happen with Tadalafil Tablets. Tadalafil Tablets do not:

- cure ED
- increase a man's sexual desire
- protect a man or his partner from sexually transmitted diseases including HIV. Speak to your healthcare provider about ways to guard against sexually transmitted diseases.
- serve as a male form of birth control

Tadalafil Tablets are only for men over the age of 18, including men with diabetes or who have undergone prostatectomy.

**Tadalafil Tablets for the Treatment of Symptoms of BPH**  
BPH is a condition that happens in men, where the prostate gland enlarges which can cause urinary symptoms.

**Tadalafil Tablets for the Treatment of ED and Symptoms of BPH**  
ED and symptoms of BPH may happen in the same person and at the same time. Men who have both ED and symptoms of BPH may take Tadalafil Tablets for the treatment of both conditions. Tadalafil Tablets are not for women or children. Tadalafil Tablets must be used only under a healthcare provider's care.

**Who Should Not Take Tadalafil Tablets?**  
Do not take Tadalafil Tablets if you:

- take any medicines called "nitrates", use recreational drugs called "poppers" like amyl nitrite and butyl nitrite. (See "What Is the Most Important Information I Should Know About Tadalafil Tablets?")
- take any medicines called guanylate cyclase stimulators, such as rosiglitazone
- are allergic to Tadalafil Tablets or ADCIRCA™, or any of its ingredients. See the end of this leaflet for a complete list of ingredients in Tadalafil Tablets. Symptoms of an allergic reaction may include:

- rash
- hives
- swelling of the lips, tongue, or throat
- difficulty breathing or swallowing

Call your healthcare provider or get help right away if you have any of the symptoms of an allergic reaction.

**What Should I Tell My Healthcare Provider Before Taking Tadalafil Tablets?**  
Tadalafil Tablets are not right for everyone. Only your healthcare provider and you can decide if Tadalafil Tablets are right for you. Before taking Tadalafil Tablets, tell your healthcare provider about all your medical problems, including if you:

- have heart problems such as angina, heart failure, irregular heartbeats, or have had a heart attack. Ask your healthcare provider if it is safe for you to have sexual activity. You should not take Tadalafil Tablets if your healthcare provider has told you not to have sexual activity because of your health problems.
- have pulmonary hypertension
- have low blood pressure or have high blood pressure that is not controlled
- have had a stroke
- have liver problems
- have kidney problems or require dialysis (runs in families) eye disease
- have ever had severe vision loss, including a condition called NAION
- have stomach ulcers
- have a bleeding problem
- have a deformed penis shape or Peyronie's disease
- have had an erection that lasted more than 4 hours
- have blood cell problems such as sickle cell anemia, multiple myeloma, or leukemia

**Can Other Medicines Affect Tadalafil Tablets?**  
Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Based on your medical history, your healthcare provider may affect each other. Always check with your healthcare provider before starting or stopping any medicines. 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 Tadalafil Tablets?")
- medicines called guanylate cyclase stimulators, such as rosiglitazone (Avanpose™), used to treat pulmonary hypertension
- medicines called alpha-blockers. These include Hymen™ (terazosin HCl), Flomax™ (tamsulosin HCl), Cardura® (doxazosin mesylate), Minipress® (prazosin HCl), Uroxatral® (alfuzosin HCl), Jalmi® (dutasteride and tamsulosin HCl) or Rapaflo® (silodosin).
- Alpha-blockers are sometimes prescribed for prostate problems or high blood pressure. If Tadalafil Tablets are taken with certain alpha-blockers, your blood pressure could suddenly drop. You could get dizzy or faint.
- other medicines to treat high blood pressure (hypertension)
- medicines called HIV protease inhibitors, such as ritonavir (Norvir®), Kaletra™
- some types of oral antifungals such as ketoconazole (Nizoral®), itraconazole (Sporanox®)
- some types of antibiotics such as clarithromycin (Biaxin®), telithromycin (Ketek®), erythromycin (several brand names exist)
- Please consult your healthcare provider to determine if you are taking this medicine.
- other medicines or treatments for ED.
- Tadalafil Tablets are also marketed as ADCIRCA for the treatment of pulmonary hypertension.
- Do not take both Tadalafil Tablets and ADCIRCA. Do not take sildenafil citrate (Revatio™) with Tadalafil Tablets.

**How Should I Take Tadalafil Tablets?**  
Take Tadalafil Tablets exactly as your healthcare provider prescribes it. Your healthcare provider will prescribe the dose that is right for you.

Some men can only take a low dose of Tadalafil Tablets or may have to take it less often, because of medical conditions or medicines they take.

Do not change your dose or the way you take Tadalafil Tablets without talking to your healthcare provider. Your healthcare provider may lower or raise your dose, depending on how your body reacts to Tadalafil Tablets and your health condition.

Tadalafil Tablets may be taken with or without food.

If you take two or more Tadalafil Tablets, call your healthcare provider or emergency room right away.

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use TADALAFIL TABLETS safely and effectively. See the full prescribing information for TADALAFIL TABLETS. TADALAFIL TABLETS are for oral use. Initial U.S. Approval: 2003**  
**INDICATIONS AND USAGE**—Tadalafil Tablets are indicated for the treatment of erectile dysfunction (ED) (1), and the signs and symptoms of benign prostatic hyperplasia (BPH) (2).

**CONTRAINDICATIONS**—Tadalafil Tablets are contraindicated in patients taking any form of organic nitrate is used for the treatment of ED or BPH. (5.1)

**WARNINGS AND PRECAUTIONS**—Tadalafil Tablets are contraindicated in patients taking any form of organic nitrate is used for the treatment of ED or BPH. (5.1)

**ADVERSE REACTIONS**—The most common adverse reactions (≥5%) include headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb

**USE IN SPECIFIC POPULATIONS**—Tadalafil Tablets should be used with caution in patients with renal impairment (2.5, 6.8, 6.9)

**CLINICAL PHARMACOLOGY**—Tadalafil Tablets are selective inhibitors of PDE5. In patients with ED, tadalafil increases the rigidity of the penis by increasing the blood flow to the penis.

**HOW SUPPLIED**—Tadalafil Tablets are available in 2.5 mg, 5 mg, and 10 mg strengths.

**STORAGE AND HANDLING**—Tadalafil Tablets should be stored at controlled room temperature (20° to 25°C).

**REFERENCES**—See full prescribing information for Tadalafil Tablets for references to clinical studies.

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risks. Individuals with "crowded" optic discs are also considered at greater risk for NAION compared to the general population. It is important to be aware of the signs and symptoms of NAION. NAION is a condition that causes vision loss in one or both eyes. It is caused by a sudden decrease in blood flow to the optic nerve. NAION is a serious condition and can lead to permanent vision loss. NAION is more likely to occur in individuals with a "crowded" optic disc. NAION is also more likely to occur in individuals with a history of NAION. NAION is also more likely to occur in individuals with a history of retinitis pigmentosa. NAION is also more likely to occur in individuals with a history of diabetes. NAION is also more likely to occur in individuals with a history of high blood pressure. NAION is also more likely to occur in individuals with a history of glaucoma. NAION is also more likely to occur in individuals with a history of macular degeneration. NAION is also more likely to occur in individuals with a history of stroke. NAION is also more likely to occur in individuals with a history of heart disease. NAION is also more likely to occur in individuals with a history of kidney disease. NAION is also more likely to occur in individuals with a history of liver disease. NAION is also more likely to occur in individuals with a history of thyroid disease. NAION is also more likely to occur in individuals with a history of autoimmune disease. NAION is also more likely to occur in individuals with a history of cancer. NAION is also more likely to occur in individuals with a history of surgery. NAION is also more likely to occur in individuals with a history of trauma. NAION is also more likely to occur in individuals with a history of infection. NAION is also more likely to occur in individuals with a history of injury. NAION is also more likely to occur in individuals with a history of abnormal blood vessel structure. NAION is also more likely to occur in individuals with a history of abnormal blood vessel function. NAION is also more likely to occur in individuals with a history of abnormal blood vessel flow. NAION is also more likely to occur in individuals with a history of abnormal blood vessel pressure. NAION is also more likely to occur in individuals with a history of abnormal blood vessel diameter. NAION is also more likely to occur in individuals with a history of abnormal blood vessel length. NAION is also more likely to occur in individuals with a history of abnormal blood vessel branching. NAION is also more likely to occur in individuals with a history of abnormal blood vessel tortuosity. NAION is also more likely to occur in individuals with a history of abnormal blood vessel curvature. NAION is also more likely to occur in individuals with a history of abnormal blood vessel angulation. NAION is also more likely to occur in individuals with a history of abnormal blood vessel constriction. NAION is also more likely to occur in individuals with a history of abnormal blood vessel dilation. NAION is also more likely to occur in individuals with a history of abnormal blood vessel aneurysm. NAION is also more likely to occur in individuals with a history of abnormal blood vessel dissection. NAION is also more likely to occur in individuals with a history of abnormal blood vessel embolism. NAION is also more likely to occur in individuals with a history of abnormal blood vessel thrombosis. NAION is also more likely to occur in individuals with a history of abnormal blood vessel stenosis. NAION is also more likely to occur in individuals with a history of abnormal blood vessel occlusion. NAION is also more likely to occur in individuals with a history of abnormal blood vessel obstruction. 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NAION is also more likely to occur in individuals with a history of abnormal blood vessel hardening. NAION is also more likely to occur in individuals with a history of abnormal blood vessel brittleness. NAION is also more likely to occur in individuals with a history of abnormal blood vessel fragility. NAION is also more likely to occur in individuals with a history of abnormal blood vessel weakness. NAION is also more likely to occur in individuals with a history of abnormal blood vessel strength. NAION is also more likely to occur in individuals with a history of abnormal blood vessel elasticity. NAION is also more likely to occur in individuals with a history of abnormal blood vessel inelasticity. NAION is also more likely to occur in individuals with a history of abnormal blood vessel compliance. NAION is also more likely to occur in individuals with a history of abnormal blood vessel non-compliance. NAION is also more likely to occur in individuals with a history of abnormal blood vessel distensibility. NAION is also more likely to occur in individuals with a history of abnormal blood vessel non-distensibility. NAION is also more likely to occur in individuals with a history of abnormal blood vessel contractility. NAION is also more likely to occur in individuals with a history of abnormal blood vessel non-contractility. NAION is also more likely to occur in individuals with a history of abnormal blood vessel relaxability. NAION is also more likely to occur in individuals with a history of abnormal blood vessel non-relaxability. NAION is also more likely to occur in individuals with a history of abnormal blood vessel tone. NAION is also more likely to occur in individuals with a history of abnormal blood vessel atonia. NAION is also more likely to occur in individuals with a history of abnormal blood vessel spasm. NAION is also more likely to occur in individuals with a history of abnormal blood vessel cramp. NAION is also more likely to occur in individuals with a history of abnormal blood vessel twitch. NAION is also more likely to occur in individuals with a history of abnormal blood vessel tremor. NAION is also more likely to occur in individuals with a history of abnormal blood vessel vibration. NAION is also more likely to occur in individuals with a history of abnormal blood vessel numbness. NAION is also more likely to occur in individuals with a history of abnormal blood vessel tingling. NAION is also more likely to occur in individuals with a history of abnormal blood vessel burning. NAION is also more likely to occur in individuals with a history of abnormal blood vessel coldness. NAION is also more likely to occur in individuals with a history of abnormal blood vessel warmth. NAION is also more likely to occur in individuals with a history of abnormal blood vessel dryness. 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**USE IN SPECIFIC POPULATIONS**—Tadalafil Tablets should be used with caution in patients with renal impairment (2.5, 6.8, 6.9)

**CLINICAL PHARMACOLOGY**—Tadalafil Tablets are selective inhibitors of PDE5. In patients with ED, tadalafil increases the rigidity of the penis by increasing the blood flow to the penis.

**HOW SUPPLIED**—Tadalafil Tablets are available in 2.5 mg, 5 mg, and 10 mg strengths.

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**FOR MORE INFORMATION**—Visit our website at [www.adva.com](http://www.adva.com).

**Full Prescribing Information**—See full prescribing information for Tadalafil Tablets.

