

# Patient Information

## Tadalafil (ta da 'il) 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 cause your 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 stimulating drug. 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 such as amyl nitrite and butyl nitrite. Nitrates are also 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:

- Riociguat (Adempas®) a medicine that treats pulmonary arterial hypertension and 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 riociguat. (See "Who Should Not Take Tadalafil Tablets?")

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 of 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 if you are taking certain other medicines (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. See also "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:

- men with 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 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 are used 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 riociguat, or Adempas®, 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 listed above.

What Should I Tell My Healthcare Provider About 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 use 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 kidney problems
- have liver problems
- have kidney problems or require dialysis
- have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- have ever had severe vision loss, including blindness (Cherry Red Spot)
- 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. Tadalafil Tablets and other medicines 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 riociguat (Adempas®), used to treat pulmonary hypertension
- recreational drugs called "poppers" such as amyl nitrite (terazolin HCl), Flomax® (tamsulosin HCl), Cardura® (doxazosin mesylate), Minipress® (prazosin HCl), Uroxatral® (alfuzosin HCl), Jalmy® (tamsulosin HCl) and tamsulosin (Ropecia®) (tulosin).
- other medicines or treatments for ED
- Tadalafil Tablets are also marketed as ADCIRCA for the treatment of pulmonary arterial hypertension. Do not take Tadalafil Tablets and ADCIRCA. Do not take Tadalafil Tablets and other medicines that have already been taken together.

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 meals.

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

# Highlights of Important Information

## Information that should be included in the prescribing information for use as Tadalafil Tablets, USP. See full prescribing information for use as Tadalafil Tablets, USP.

### INDICATIONS AND USAGE

Tadalafil Tablets are indicated for the treatment of:

- erectile dysfunction (ED)
- symptoms of benign prostatic hyperplasia (BPH)

Tadalafil Tablets are indicated for the treatment of ED and symptoms of BPH in men who have both ED and symptoms of BPH.

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

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- have pulmonary hypertension
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# Warnings and Precautions

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- nitroglycerin
- isosorbide dinitrate
- isosorbide mononitrate
- amyl nitrite
- butyl nitrite

Do not take Tadalafil Tablets if you are taking any of the following medicines:

- riociguat (Adempas®)
- any other medicine that contains a guanylate cyclase stimulator

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# Adverse Reactions

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The most common adverse reactions (≥10%) include:

- headache
- dizziness
- nasal congestion
- back pain
- myalgia
- flushing
- indigestion
- diarrhea
- abdominal pain
- nasal congestion
- back pain
- myalgia
- flushing
- indigestion
- diarrhea
- abdominal pain

Other adverse reactions include:

- hypotension
- syncope
- retinitis pigmentosa
- bleeding events
- prolonged erection
- priapism
- vision changes
- hypertension
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