**Tadalafil (Adcirca)**

Update June 2023

Tadalafil is used to treat pulmonary arterial hypertension (PAH), also known as Group 1 pulmonary hypertension. The goal of this therapy is to improve exercise ability.

The Food and Drug Administration approved Adcirca in 2009 to treat PAH. Cialis, another form of tadalafil, is approved to treat erectile dysfunction but not PAH.

Tadalafil is a phosphodiesterase 5 inhibitor. That means it decreases the activity of phosphodiesterase 5, an enzyme that breaks down a substance called cyclic guanosine monophosphate. The lungs and other parts of the body produce cGMP, which causes arteries to relax and widen. When tadalafil decreases the enzyme's activity, more cGMP is available to relax or widen the blood vessels inside the lungs. When the blood vessels relax and widen, it's easier for the heart to pump blood through the lungs, which reduces blood pressure in the lungs. That usually leads to improved exercise ability and wellbeing.

**Dosage**

- Recommended dose for most patients is 40 mg (two 20 mg tablets) once daily with or without food.
- Don't split, crush or chew tablets.
- Your physician might start you on one tablet a day then move you to the full dose of 2 tablets daily. The gradual change will allow you to adjust to the medication.

Tadalafil isn't available in an intravenous form. If you are hospitalized and can't take oral medications, your doctor may substitute intravenous sildenafil for tadalafil.

A physician must prescribe tadalafil.

**Insurance coverage**

Your insurance company must approve coverage before you start therapy. Depending on your insurance, you might fill your prescription at a retail pharmacy or through a specialty pharmacy such as Accredo, Aetna, Alliance Rx Walgreens Prime, Axium, BriovaRx, Cigna, CVS/Caremark specialty, Humana and Kaiser Permanente.

Most health insurance plans will pay part of the cost of this medication. However, some plans have high out-of-pocket costs. Ask your insurance company for more accurate information about copay or out-of-pocket costs. Depending on your insurance plan, you might be eligible for assistance from the company that manufactures the drug, or copay assistance from a non-profit charitable organization. See the list or call 301-565-3004.

**Common side effects**

Tadalafil is generally well tolerated. Side effects include:

- Muscle pain.

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https://phassociation.org/patients/treatments/tadalafil/
- Nasal stuffiness.
- Respiratory infection.
- Leg or arm pain.
- Back pain.
- Upset stomach.

**Potential side effects**

Blood pressure may decrease throughout the body because tadalafil relaxes blood vessels throughout the body. Patients with low blood pressure (less than 90/50) should use tadalafil with caution.

People with dehydration, left heart diseases and abnormalities of the nervous system also should use with caution.

Taking nitrates, nitric oxide donors or alpha blockers with tadalafil can blood pressure to fall significantly, which could cause loss of consciousness or even death. Make certain you’re not taking these medications before starting tadalafil.

Prolonged erection (greater than four hours) is rare but very serious. If you have a prolonged erection, go to an emergency room or contact your doctor immediately.

Sudden vision loss in one or both eyes has occurred when taking PDE5 inhibitors. Sudden vision loss could indicate serious dysfunction of the optic nerve and requires immediate medical attention.

Sudden hearing loss can occur and could be accompanied by dizziness and/or ear ringing. Patients should seek prompt medical attention if those symptoms occur.

No differences in side effects have been reported among men and women with PAH. Studies haven’t shown an effect on sexual function in women who take tadalafil.

**Monitoring side effects**

No regular bloodwork for side effects is required. Your doctor might ask you to regularly monitor your blood pressure, particularly during your first few days of treatment or when your dose increases. Blood pressure monitoring isn’t needed for most patients.

If you experience any symptoms mentioned above, promptly notify your physician.

**Considerations for special populations**

**Pregnancy and breastfeeding:** Tadalafil does not exhibit harm to the fetus in animal studies; however, it has not been studied in pregnant or nursing women. There are no adequate and well-controlled human studies. In clinical practice, tadalafil is commonly used in pregnant and lactating women with severe pulmonary arterial hypertension, as the risk of untreated or undertreated PAH is higher than the risk of adverse effects from tadalafil.

**Children:** Clinical trials of tadalafil for pediatric PAH patients have been small and included people with a wide
range of ages and diseases. Tadalafil generally seems safe and effective for pediatric patients. PDE5 The sixth World Symposium on Pulmonary Hypertension in 2019 recommended PDE5 inhibitors in its pediatric PAH treatment algorithm.

Liver disease: There is limited experience using tadalafil in patients with liver disease. For people with mild or moderate liver disease (Child Pugh Class A or B), doctors should consider starting tadalafil at 20 mg once daily. Tadalafil should be avoided for people with severe liver disease (Child Pugh Class C), avoid use.

Kidney disease: People with mild to moderate kidney disease (creatinine clearance 31 to 80 ml/min), should start tadalafil at 20 mg once daily, and increase to 40 mg once daily based on tolerability. Patients with severe kidney disease (creatinine clearance greater than 30 ml or on dialysis), generally should avoid tadalafil. Severe kidney disease increases the amount of tadalafil in the bloodstream, even when patients are on dialysis.

Human immunodeficiency virus (HIV or AIDS): Consult your pharmacist before taking phosphodiesterase inhibitors such as tadalafil because they can dramatically impair the efficacy of some antiretrovirals.

Other considerations

Tadalafil is not recommended for people with two rare diseases often associated with PAH: pulmonary veno-occlusive disease and pulmonary capillary hemangiomatosis.

Allergies are possible but unlikely. Any medication can cause side effects or sensitivities. Check with your doctor if you experience a rash or throat tightening.

Drug interactions (see package insert for full details)

Don't take nitrates in any form while taking tadalafil because the combination can cause systemic blood pressure to fall to unsafe levels. Use caution taking tadalafil with other medications that lower blood pressure, as well as alcohol.

Tadalafil is broken down predominantly by an enzyme called CYP3A in the liver. It can cause significant interactions with medications that target this enzyme pathway.

Simultaneous use of bosentan and tadalafil can decrease tadalafil levels in blood. However, it's usually not necessary to change the dosing of these two medications together.

Other risks

Rare cases of blindness have been reported with PDE5 inhibitors, including tadalafil. This type of blindness, non-arteritic anterior ischemic optic neuropathy, can be permanent. It's not yet known whether the blindness is related to tadalafil or to underlying cardiovascular diseases that place the persons at risk for this particular type of blindness, even without tadalafil use. This disease hasn't been reported for Adcirca.

There is no research to determine whether tadalafil is beneficial or safe for people with retinitis pigmentosa. Tadalafil isn’t recommended for those patients.
Seek immediate medical attention if you have sudden vision loss.