

Patient Information

Tadalafil (tah-DA-la-fil) tablets USP

Read this patient information before you start taking tadalafil tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about tadalafil tablets?

Never take tadalafil tablets with any nitrate or guanylate cyclase stimulator medicines:

- Your blood pressure could drop quickly to an unsafe level
- You could get dizzy, faint and even have a heart attack or stroke.

Nitrates include:

- Medicines that treat chest pain (angina)
- Nitroglycerin in any form including tablets, patches, sprays, and ointments
- Other nitrate medicines (isosorbide mononitrate or dinitrate)
- Street drugs that are inhaled, called “poppers” (amyl nitrate, butyl nitrate or nitrite)

Guanylate cyclase stimulators 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 you take nitrate or guanylate cyclase stimulator medicine.

What are tadalafil tablets?

Tadalafil tablets are a prescription medicine used to treat pulmonary arterial hypertension (PAH, high blood pressure in your lungs) to improve your ability to exercise.

It is not known if tadalafil tablets are safe or effective in children.

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 or nitrite.
- take any medicines called guanylate cyclase stimulators.
- are allergic to tadalafil or any other ingredients in tadalafil tablets. See “**What are the ingredients in tadalafil tablets?**” at the end of this leaflet.

See “**What is the most important information I should know about tadalafil tablets?**”

What should I tell my healthcare provider before taking tadalafil tablets?

Before taking tadalafil tablets, tell your healthcare provider about all of your medical conditions, including if you:

- are allergic to tadalafil tablets or any of its ingredients. See the end of this leaflet for a complete list of ingredients in tadalafil tablets.
- have pulmonary veno-occlusive disease (PVOD)
- have heart problems

- have low blood pressure
- have liver problems
- have kidney problems or get dialysis
- have retinitis pigmentosa, a rare genetic eye disease
- have ever had any sudden vision loss, including any damage to your optic nerve or NAION.
- have ever had hearing problems such as ringing in the ears, dizziness, or loss of hearing
- 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
- are pregnant or planning to become pregnant. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breast feed. If you breastfeed while taking tadalafil tablets, it is likely that tadalafil will pass into your breast milk. You and your healthcare provider should decide if you will take tadalafil tablets or breastfeed. You should not do both.

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.

Especially tell your healthcare provider if you take any of these medicines*:

- nitrates or guanylate cyclase stimulators (see “**What is the most important information I should know about tadalafil tablets?**”)
- alpha blockers, used to treat prostate disease and high blood pressure. Your blood pressure could suddenly drop. You could get dizzy or faint.
- protease inhibitors, used to treat HIV infection, such as ritonavir (Norvir[®], Kaletra[®])
- ketoconazole (Extina[®], Xolegel[®], Ketozone[®], Nizoral A-D[®], Nizoral[®]) itraconazole (Sporanox[®])
- erythromycin (several brand names exist. Please consult your healthcare provider to determine if you are taking this medicine)
- rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®])
- bosentan (Tracleer[®])
- phenobarbital, phenytoin (Dilantin[®]), carbamazepine (Tegretol[®])
- CIALIS[®] or other medicines or treatments for erectile dysfunction (impotence).
- Tadalafil tablets are also marketed as CIALIS for the treatment of male erectile dysfunction (ED, impotence) and for the signs and symptoms of benign prostatic hyperplasia (BPH, enlarged prostate). Do not take both tadalafil tablets and CIALIS. Do not take tadalafil tablets and other medicines or treatments for erectile dysfunction.

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take tadalafil tablets?

- Take tadalafil tablets exactly as your healthcare provider tells you.

- Take tadalafil tablets at the same time every day. You should take both tablets at the same time, one after the other, every day. Do not split your dose.
- Tadalafil tablets can be taken with or without food.
- Do not change your dose or stop taking tadalafil tablets without speaking to your healthcare provider.
- If you take too much tadalafil tablets, call your healthcare provider or go to an emergency department right away.

What should I avoid while taking tadalafil tablets?

Do not have more than 4 alcohol-containing drinks in a short period of time while you take tadalafil tablets. Drinking too much alcohol can lower your blood pressure. You could get dizzy or faint.

What are the possible side effects of tadalafil tablets?

The following side effects were reported rarely in patients taking tadalafil:

- Decreased eyesight or loss of vision in one or both eyes (NAION). If you notice a sudden decrease or loss of vision in one or both eyes, contact a healthcare provider right away.
- Sudden decrease or loss of hearing, sometimes with ringing in the ears and dizziness. If you notice a sudden decrease or loss of hearing, contact a healthcare provider right away.
- **In men, an erection that lasts more than 4 hours (with or without pain).** Talk to your healthcare provider or go to the emergency department right away. **An erection that lasts more than 4 hours** must be treated as soon as possible or you can have lasting damage to your penis, including the inability to have erections.

See **“What is the most important information I should know about tadalafil tablets?”**

The most common side effects with tadalafil tablets include:

- headache
- muscle pain
- getting red or hot in the face (flushing)
- nausea
- pain in the arms, legs, or back
- upset stomach
- stuffy or congested nose

Tell your healthcare provider about any side effect that bothers you or does not go away.

These are not all the possible side effects of tadalafil tablets. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How Should I Store tadalafil tablets?

Store tadalafil tablets USP at room temperature between 59° and 86°F (15° and 30°C).

Keep tadalafil tablets and all medicines out of the reach of children.

General information about the safe and effective use of tadalafil tablets:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use tadalafil tablets for a condition for which it was not prescribed. Do not give tadalafil tablets to other people, even if they have the same symptoms you have. It may harm them.

This patient information leaflet summarizes the most important information about tadalafil tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about tadalafil tablets that is written for healthcare professionals. For more information, call 1-800-912-9561.

What Are the Ingredients in tadalafil tablets USP?

Active Ingredient: tadalafil USP

Inactive Ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry® II Yellow, and sodium lauryl sulfate.

The color coating material contains following ingredients.

Strength	Coating material	Ingredients
20 mg	Opadry® II Yellow	HPMC 2910 / Hypromellose, Iron oxide yellow, Lactose monohydrate, Talc, Titanium dioxide, Triacetin.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Manufactured by:

TORRENT PHARMACEUTICALS LTD., INDIA.

Manufactured for

TORRENT PHARMA INC., Basking Ridge, NJ 07920.

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