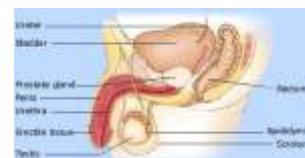
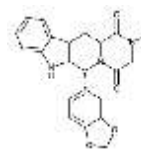


Rx TADALAFIL

(Tadalafil is an oral drug. It is in a class of drugs called phosphodiesterase inhibitors)



DRUG CLASS AND MECHANISM

Tadalafil is an oral drug that is used for treating impotence (the inability to attain or maintain a penile erection). It is in a class of drugs called phosphodiesterase inhibitors that also includes sildenafil (Viagra) and vardenafil (Levitra).

Erection of the penis is caused by the filling of the penis with blood. Filling occurs because the blood vessels that bring blood to the penis increase in size and deliver more blood to the penis, and, at the same time, the blood vessels that take blood away from the penis decrease in size and remove less blood from the penis.

Sexual stimulation that leads to an erection causes the production and release of nitric oxide in the penis. The nitric oxide causes an enzyme, guanylate cyclase, to produce cyclic guanosine monophosphate (cGMP). It is the cGMP that is primarily responsible for increasing and decreasing the size of the blood vessels carrying blood to and from the penis, respectively, and causing the erection. When the cGMP is destroyed by another enzyme, phosphodiesterase-5, the blood vessels return to their normal size, blood leaves the penis, and the erection ends. Tadalafil prevents phosphodiesterase-5 from destroying cGMP so that cGMP stays around longer. The persistence of cGMP leads to a more prolonged engorgement of the penis with blood.

Tadalafil was approved by the FDA in November 2003.

PRESCRIPTION: Yes.

GENERIC AVAILABLE: No.

PREPARATIONS: Tablets: 5, 10, and 20 mg.

PRESCRIBED FOR

Tadalafil is used for the treatment of impotence (erectile dysfunction, ED).

DOSING

For most individuals, the recommended starting dose of tadalafil is 10 mg per day taken before sexual activity. Depending on the adequacy of the response or side effects, the dose may be increased to 20 mg or decreased to 5 mg a day. The effect of tadalafil may last up to 36 hours. Individuals who are taking medications that increase the blood levels of tadalafil should not exceed a total dose of 10 mg in 72 hours (See drug interactions). Tadalafil may be taken with or without food since food does not affect its absorption from the intestine.

DRUG INTERACTIONS

The breakdown and elimination of tadalafil from the body may be decreased by erythromycin, ketoconazole (Nizoral), itraconazole (Sporanox), indinavir (Crixivan) and ritonavir (Norvir). Therefore, these drugs may increase the levels of tadalafil in the blood. If these drugs are being used at the same time as tadalafil, the dose of tadalafil should be reduced in order to avoid side effects from high levels of tadalafil.

Tadalafil exaggerates the increases in heart rate and lowering of blood pressure caused by nitrates, for example, nitroglycerin, isosorbide dinitrate (Isordil), isosorbide mononitrate (Imdur, Ismo, Monoket), nitroglycerin (Nitro-Dur, Transderm-Nitro) that are used primarily for treating heart pain (angina). In patients who take nitrates for angina, tadalafil could cause heart pain or possibly even a heart attack by exaggerating the increase in heart rate and the lowering of blood pressure. Therefore, tadalafil should not be used with nitrates.

Tadalafil also exaggerates the blood pressure lowering effects of some alpha-blocking drugs for example, terazosin (Hytrin) that primarily are used for treating high blood pressure or enlargement of the prostate. Individuals who take these alpha-blockers should be on a stable dose of the alpha-blocker before tadalafil is started. In such situations, tadalafil should be started at the lowest dose. If the patient is already taking tadalafil, the alpha-blocker should be started at the lowest dose. Tadalafil and alcohol both lower blood pressure. Therefore, combining tadalafil with alcohol may cause excessive drops in blood pressure and cause dizziness, headaches, and increased heart rate.

USES

Tadalafil is used to treat male sexual function problems (impotence or

erectile dysfunction) by blocking a certain enzyme (phosphodiesterase-PDE5) in the body. In combination with sexual stimulation, tadalafil helps blood flow into the penis to achieve and maintain an erection. This drug is not indicated for use in women. Use of this drug does not protect against sexually transmitted diseases (e.g., HIV, hepatitis B, gonorrhea, syphilis). Practice "safe sex" such as using latex condoms. Consult your doctor or pharmacist for more details.

HOW TO USE

Read the patient information leaflet provided by your pharmacist and ask questions if any of the information is unclear. Take this medication by mouth with or without food as directed by your doctor. There are two ways that this drug may be prescribed and taken. It may be taken as needed, or it may be taken once a day every day. Your doctor will determine which is the best way for you to take this drug. Follow your doctor's directions exactly. If used regularly every day, your doctor will prescribe a low dose (usually 2.5 to 5 milligrams per day). When this drug is taken only as needed, the dosing may need to be higher. Never take more of this drug than prescribed because you may experience serious side effects. Your doctor will adjust your dosage based on your response and other medications you may be taking (see also Drug Interactions section). Consult your doctor or pharmacist for more details. When taken as needed, take this drug at least 30 minutes before sexual activity; or use as directed by your doctor. This medication's effect on sexual ability may last up to 36 hours. Therefore, do not take more than once daily as needed. When taken regularly every day, you may attempt sexual activity at any time between your doses. Do not take more than one dose each day. Avoid eating grapefruit or drinking grapefruit juice while being treated with this medication unless your doctor instructs you otherwise. Grapefruit juice can increase the amount of certain medications in your bloodstream. Consult your doctor or pharmacist for more details.

SIDE EFFECTS

Headache, stomach upset, back pain, muscle pain, nasal stuffiness, flushing, pain in arms or legs, dizziness, or vision changes may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Rarely, a sudden loss of eyesight in one or both eyes (NAION) may occur. This may or may not be due to tadalafil. If this serious problem occurs, seek immediate medical attention. You have a slightly greater chance of developing this serious eye problem if you have heart disease, diabetes, high cholesterol, certain eye problems ("crowded disk"), high blood pressure, are over 50 years of age, or if you smoke. Sexual activity may put extra strain on your heart, especially if you have heart problems. If you have heart problems or experience any of the following serious side effects during sex, stop and seek immediate medical attention: severe dizziness, fainting, chest pain. For males, in the very unlikely event you have a painful or prolonged erection lasting 4 or more hours, stop using this drug and seek immediate medical attention, or permanent problems could occur. Rarely, tadalafil may cause sudden hearing problems, or ringing in the ears. Stop taking this medication and tell your doctor immediately if these effects occur. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking tadalafil, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: penis conditions (e.g., angulation, fibrosis/scarring, Peyronie's disease), history of painful/prolonged erection (priapism), sickle cell anemia, blood system cancers (e.g., leukemia or myeloma), eye problems (e.g., retina diseases like retinitis pigmentosa), kidney disease, liver disease, bleeding disorders, active stomach ulcers, heart problems (e.g., recent heart attack or serious arrhythmia within past 6 months, heart failure, coronary artery disease with unstable angina, aortic stenosis, idiopathic hypertrophic subaortic stenosis), recent stroke within past 6 months, very high or low blood pressure. This drug may make you dizzy or cause vision changes. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. This drug is not indicated for use in women or children.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you are taking this medication on a regular schedule and you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59 and 86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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