





GENERIC NAME: sildenafil

DRUG CLASS AND MECHANISM

It has been estimated that impotence (erectile dysfunction, ED) affects 140 million men worldwide. Over half of all men with impotence are thought to have some physical (medical) cause. The remainder are believed to have psychogenic causes of impotence. Medical causes of impotence include diabetes and circulatory, neurological, or urological conditions.

Penile erection is caused by the engorgement of the penis with blood. This engorgement occurs when the blood vessels delivering blood to the penis increase the delivery of blood and the blood vessels carrying blood away from the penis decrease the removal of blood. Under normal conditions, sexual stimulation leads to the production and release of nitric oxide in the penis. Nitric oxide then activates the enzyme, guanylate cyclase, which causes the production of cyclic guanosine monophosphate (cGMP). It is the cGMP that is primarily responsible for the erection by affecting the amount of blood that the blood vessels deliver and remove from the penis.

Sildenafil also reduces the pressure in the pulmonary artery in a serious condition called pulmonary arterial hypertension.

Sildenafil inhibits an enzyme called phosphodiesterase-5 (PDE5) which destroys the cGMP. Thus, sildenafil prevents the destruction of cGMP and allows cGMP to accumulate and persist longer. The longer cGMP persists, the more prolonged the engorgement of the penis.

PRESCRIPTION: Yes

GENERIC AVAILABLE: No

PREPARATIONS

Viagra is a blue, film-coated, rounded, diamond-shaped tablet that comes in 25, 50, and 100 mg tablets for treating impotence. Revatio comes in a 20 mg tablet and is used for treating pulmonary arterial hypertension.

PRESCRIBED FOR

Sildenafil is used for the treatment of erectile dysfunction of either organic (medical condition) or psychogenic (psychological) cause and for pulmonary arterial hypertension.

DOSING

Sildenafil is rapidly absorbed. Maximum observed plasma concentrations are reached within 30 to 120 minutes (median 60 minutes) of oral dosing in the fasted state. When sildenafil is taken with a high fat meal, the rate of absorption is reduced, with an average delay in the time to maximal concentration of 1 hour.

DRUG INTERACTIONS

See also How To Use section for drug-food interactions. This drug should not be used with the following medications because very serious (possibly fatal) interactions may occur: nitrates (e.g., nitroglycerin, isosorbide), nitroprusside (or any "nitric oxide donor" drugs), recreational drugs called "poppers" containing amyl or butyl nitrite. If you are currently using any of these medications, tell your doctor or pharmacist before starting sildenafil. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription products you may use, especially of: other medications for impotence, azole antifungals (e.g., itraconazole, ketoconazole), cimetidine, erythromycin, mibefradil, rifamycins (e.g., rifampin), high blood-pressure medicines, delavirdine. If you are taking an HIV protease inhibitor (e.g., ritonavir, saquinavir), do not take more than a 25mg dose of sildenafil in a 48 hour period. If you are taking more than a 25mg dose of sildenafil and are also taking an alpha-blocker medication (e.g., doxazosin, prazosin, terazosin) for various conditions (e.g., enlarged prostate), separate the time between taking these medications by more than 4 hours. Do not start or stop any medicine without doctor or pharmacist approval.

USES

Sildenafil 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, sildenafil works by helping the 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

This drug is taken by mouth as needed, at least 30 minutes, but no more than 4 hours, before sexual activity (1 hour before is the most effective). Do not take more often than once daily, and take as directed. A high fat meal may delay the time of onset of this drug. Avoid eating grapefruit or drinking grapefruit juice while you are being treated with this medication unless your doctor instructs you otherwise. The dosage is based on your medical condition, response to therapy, and other medications you may be taking (see also Drug Interactions section). Consult your doctor or pharmacist for more details.

SIDE EFFECTS

Headache, flushing, stomach upset, heartburn, nasal stuffiness, diarrhea, dizziness, or lightheadedness may occur. Vision changes such as increased sensitivity to light, blurred vision, or impaired blue/green color discrimination may also occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Sexual activity may put extra strain on your heart, especially if you have heart problems. If you have heart problems and experience any of these serious side effects while having sex, stop and tell your doctor immediately of: severe dizziness, fainting, chest pain, nausea. In the unlikely event you have a painful or prolonged erection (lasting more than 4 hours), stop using this drug and seek immediate medical attention or permanent problems could 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, unusual swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking sildenafil, 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; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug. 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. Symptoms of overdose may include severe dizziness, fainting, or prolonged erection.

MISSED DOSE

Not applicable.

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.

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.



Taj Group of Companies INDIA

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91, (0)22 - 26374592/93 91 - (0)22 - 30601000,

Fax: 91-(0)22-26341274

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