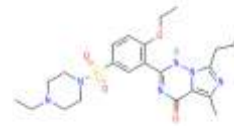


Rx VARDENAFIL

(Vardenafil is an oral drug that is used to treat impotence)



GENERIC NAME: vardenafil

DRUG CLASS AND MECHANISM: Vardenafil is an oral drug that is used to treat impotence (the inability to attain or maintain a penile erection.). It is a phosphodiesterase inhibitor that is similar to sildenafil (Viagra).

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 in size and increase the delivery of blood to the penis. At the same time, the blood vessels carrying blood away from the penis decrease in size and decrease the removal of blood from the penis. Sexual stimulation that leads to the engorgement and erection causes the production and release of nitric oxide in the penis. Nitric oxide then activates the enzyme, guanylate cyclase to produce cyclic guanosine monophosphate (cGMP). The cGMP is primarily responsible for increasing and decreasing the size of the blood vessels carrying blood to and from the penis, respectively. Vardenafil prevents an enzyme called phosphodiesterase-5 from destroying cGMP so that cGMP persists longer. The longer cGMP persists, the more prolonged the engorgement of the penis. Vardenafil was approved by the FDA in August, 2003.

PRESCRIPTION: Yes

GENERIC AVAILABLE: No

PREPARATIONS: Tablets: 2.5, 5, 10 and 20 mg

PRESCRIBED FOR: Vardenafil is used for the treatment of impotence.

DOSING

For most individuals, the recommended dose of vardenafil is 10 mg per day taken 60 minutes before intercourse. If there is no response or side effects, the dose may be increased to 20 mg or, if there are side effects, it may be reduced to 5 mg. Individuals 65 years of age or older should begin therapy with 5 mg. Individuals who are taking medications that increase the blood levels of vardenafil should start treatment with 2.5 to 5 mg of vardenafil. (See drug interactions.)

DRUG INTERACTIONS

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

Vardenafil reduces the concentration of ritonavir and indinavir and may reduce the effect these drugs.

Vardenafil increases the heart rate and also exaggerates the blood pressure lowering effects of nitrates (e.g. nitroglycerine). In patients who take nitrates for chest pain (angina), vardenafil could cause chest pain by increasing heart rate and lowering blood pressure. Therefore, patients with angina should not use vardenafil. Vardenafil also exaggerates the blood pressure lowering effects of alpha-blocking drugs, e.g. terazosin (Hytrin), and should not be used by individuals who also use alpha-blockers.

USES

Vardenafil is used to treat male sexual function problems (impotence or erectile dysfunction) by blocking a certain enzyme (phosphodiesterase-PDE5). In combination with sexual stimulation, vardenafil 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, gonorrhoea, 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, 1 hour before sexual activity with or without food; or use as directed by your doctor. Do not take more often than once daily as needed. A high fat meal may decrease the amount of drug that is absorbed. 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. Read the patient information leaflet provided by your pharmacist and ask questions if any of the information is unclear.

SIDE EFFECTS

Headache, flushing, nasal stuffiness, stomach upset, heartburn, runny nose, dizziness, or nausea 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. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: fast/slow/irregular heartbeat. 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. 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 vardenafil, 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, congenital QT prolongation), 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 back pain, muscle pain, abnormal vision.

MISSED DOSE

Not applicable.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 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.



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