

Patient Information

VARDENAFIL (var-DEN-a-fil) HYDROCHLORIDE Tablets

Read the Patient Information about vardenafil hydrochloride tablets before you start taking it and again each time you get a refill. There may be new information. You may also find it helpful to share this information with your partner. This leaflet does not take the place of talking with your doctor. You and your doctor should talk about vardenafil hydrochloride tablets when you start taking it and at regular checkups. If you do not understand the information, or have questions, talk with your doctor or pharmacist.

WHAT IMPORTANT INFORMATION SHOULD YOU KNOW ABOUT VARDENAFIL HYDROCHLORIDE TABLETS?

Vardenafil hydrochloride tablets can cause your blood pressure to drop suddenly to an unsafe level if it is taken with certain other medicines. With a sudden drop in blood pressure, you could get dizzy, faint, or have a heart attack or stroke.

Do not take vardenafil hydrochloride tablets if you:

- Take any medicines called “nitrates” (often used to control chest pain, also known as angina).
- Use recreational drugs called “poppers” like amyl nitrate and butyl nitrate.
- Take riociguat (Adempas®), a guanulate cyclase stimulator, a medicine that treats pulmonary arterial hypertension and chronic-thromboembolic pulmonary hypertension.

(See “Who Should Not Take vardenafil hydrochloride tablets?”)

Tell all your healthcare providers that you take vardenafil hydrochloride tablets. If you need emergency medical care for a heart problem, it will be important for your healthcare provider to know when you last took vardenafil hydrochloride tablets.

WHAT ARE VARDENAFIL HYDROCHLORIDE TABLETS?

Vardenafil hydrochloride tablets are a prescription medicine taken by mouth for the treatment of erectile dysfunction (ED) in men.

ED is a condition where the penis does not harden and expand when a man is sexually excited, or when he cannot keep an erection. A man who has trouble getting or keeping an erection should see his doctor for help if the condition bothers him. Vardenafil hydrochloride tablets may help a man with ED get and keep an erection when he is sexually excited.

Vardenafil hydrochloride tablets do not:

- Cure ED
- Increase a man’s sexual desire
- Protect a man or his partner from sexually transmitted diseases, including HIV. Speak to your doctor about ways to guard against sexually transmitted diseases.
- Serve as a male form of birth control.

Vardenafil hydrochloride tablets are only for men with ED. Vardenafil hydrochloride tablets are not for women or children. Vardenafil hydrochloride tablets must be used only under a doctor’s care.

HOW DO VARDENAFIL HYDROCHLORIDE TABLETS WORK?

When a man is sexually stimulated, his body’s normal physical response is to increase blood flow to his penis. This results in an erection. Vardenafil hydrochloride tablets helps increase blood flow to the penis and may help men with ED get and keep an erection satisfactory for sexual activity. Once a man has completed sexual activity, blood flow to his penis decreases, and his erection goes away.

WHO CAN TAKE VARDENAFIL HYDROCHLORIDE TABLETS?

Talk to your doctor to decide if vardenafil hydrochloride tablets are right for you.

Vardenafil hydrochloride tablets have been shown to be effective in men over the age of 18 years who have erectile dysfunction, including men with diabetes or who have undergone prostatectomy.

WHO SHOULD NOT TAKE VARDENAFIL HYDROCHLORIDE TABLETS?

Do not take vardenafil hydrochloride tablets if you:

- **Take any medicines called “nitrates”** (See “What important information should you know about vardenafil hydrochloride tablets?”). Nitrates are commonly used to treat angina. Angina is a symptom of heart disease and can cause pain in your chest, jaw, or down your arm. Medicines called nitrates include nitroglycerin that is found in tablets, sprays, ointments, pastes, or patches. Nitrates can also be found in other medicines such as isosorbide dinitrate or isosorbide mononitrate. Some recreational drugs called “poppers” also contain nitrates, such as amyl nitrate and butyl nitrate. Do not use vardenafil hydrochloride tablets if you are using these drugs. Ask your doctor or pharmacist if you are not sure if any of your medicines are nitrates.
- **Take riociguat, a guanulate cyclase stimulator,** a medicine that treats pulmonary arterial hypertension and chronic-thromboembolic pulmonary hypertension.
- **Have been told by your healthcare provider to not have sexual activity because of health problems.** Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease.

WHAT SHOULD YOU DISCUSS WITH YOUR DOCTOR BEFORE TAKING VARDENAFIL HYDROCHLORIDE TABLETS?

Before taking vardenafil hydrochloride tablets, tell your doctor about all your medical problems, including if you:

- Have heart problems such as angina, heart failure, irregular heartbeats, or have had a heart attack. Ask your doctor if it is safe for you to have sexual activity.
- Have low blood pressure or have high blood pressure that is not controlled.
- Have pulmonary hypertension.
- Have had a stroke.
- Have had a seizure.
- Or any family members have a rare heart condition known as prolongation of the QT interval (long QT syndrome).
- Have liver problems.
- Have kidney problems and require dialysis.
- Have retinitis pigmentosa, a rare genetic (runs in families) eye disease
- Have ever had severe vision loss, or if you have an eye condition called non-arteritic anterior ischemic optic neuropathy (NAION).
- Have stomach ulcers.
- Have a bleeding problem.
- 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.
- Have hearing problems.

CAN OTHER MEDICATIONS AFFECT VARDENAFIL HYDROCHLORIDE TABLETS?

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Vardenafil hydrochloride tablets and other medicines may affect each other. Always check with your doctor before starting or stopping any medicines. Especially tell your doctor if you take any of the following:

- Medicines called nitrates (see “What important information should you know about vardenafil hydrochloride tablets?”).

- Ketoconazole or itraconazole (such as Nizoral® or Sporanox®).
- Ritonavir (Norvir®) or indinavir sulfate (Crixivan®) saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®).
- Erythromycin or clarithromycin.
- Medicines called alpha-blockers. These include Hytrin® (terazosin hydrochloride), Flomax® (tamsulosin hydrochloride), Cardura® (doxazosin mesylate), Minipress® (prazosin hydrochloride), Rapaflo® (silodosin) or Uroxatral® (alfuzosin hydrochloride). Alpha-blockers are sometimes prescribed for prostate problems or high blood pressure. In some patients the use of PDE5 inhibitor drugs, including vardenafil, with alpha-blockers can lower blood pressure significantly leading to fainting.
- You should contact the prescribing physician if alpha-blockers or other drugs that lower blood pressure are prescribed by another healthcare provider.
- Medicines that treat abnormal heartbeat. These include quinidine, procainamide, amiodarone and sotalol.
- Other medicines or treatments for ED.

HOW SHOULD YOU TAKE VARDENAFIL HYDROCHLORIDE TABLETS?

Take vardenafil hydrochloride tablets exactly as your doctor prescribes. **Do not take more than one vardenafil hydrochloride tablets a day.** Doses should be taken at least 24 hours apart. Some men can only take a low dose of vardenafil hydrochloride tablets because of medical conditions or medicines they take. Your doctor will prescribe the dose that is right for you.

- If you are older than 65 or have liver problems, your doctor may start you on a lower dose of vardenafil hydrochloride tablets.
- If you have prostate problems or high blood pressure, for which you take medicines called alpha-blockers, your doctor may start you on a lower dose of vardenafil hydrochloride tablets.
- If you are taking certain other medicines your doctor may prescribe a lower starting dose and limit you to one dose of vardenafil hydrochloride tablets in a 72-hour (3 days) period.

Take 1 vardenafil hydrochloride tablet about 1 hour (60 minutes) before sexual activity. Some form of sexual stimulation is needed for an erection to happen with vardenafil hydrochloride tablets. Vardenafil hydrochloride tablets may be taken with or without meals.

Do not change your dose of vardenafil hydrochloride tablets without talking to your doctor. Your doctor may lower your dose or raise your dose, depending on how your body reacts to vardenafil hydrochloride tablets.

Call your doctor or emergency room immediately if you accidentally took more vardenafil tablets than prescribed.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF VARDENAFIL HYDROCHLORIDE TABLETS?

The most common side effects with vardenafil hydrochloride tablets are headache, flushing, stuffy or runny nose, indigestion, upset stomach, dizziness or back pain. These side effects usually go away after a few hours. Call your doctor if you get a side effect that bothers you or one that will not go away.

Vardenafil hydrochloride tablets may uncommonly cause:

- **An erection that won’t go away (priapism).** If you get an erection that lasts more than 4 hours, get medical help right away. Priapism must be treated as soon as possible or lasting damage can happen to your penis including the inability to have erections.
- **Color vision changes,** such as seeing a blue tinge to objects or having difficulty telling the difference between the colors blue and green.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including vardenafil hydrochloride tablets) reported a sudden decrease or loss of vision in one or both eyes. It is not possible to determine whether these events are related directly to these medicines, to other factors such as high blood pressure or diabetes, or to a combination of these. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including vardenafil hydrochloride tablets, and call a doctor right away.

Sudden loss or decrease in hearing, sometimes with ringing in the ears and dizziness, has been rarely reported in people taking PDE5 inhibitors, including vardenafil hydrochloride tablets. It is not possible to determine whether these events are related directly to the PDE5 inhibitors, to other diseases or medications, to other factors, or to a combination of factors. If you experience these symptoms, stop taking vardenafil hydrochloride tablets and contact a doctor right away.

These are not all the side effects of vardenafil hydrochloride tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1800-FDA-1088.

HOW SHOULD VARDENAFIL HYDROCHLORIDE TABLETS BE STORED?

- Store vardenafil hydrochloride tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep vardenafil hydrochloride tablets and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT VARDENAFIL HYDROCHLORIDE TABLETS

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

This leaflet summarizes the most important information about vardenafil hydrochloride tablets. If you would like more information, talk with your healthcare provider. You can ask your doctor or pharmacist for information about vardenafil hydrochloride tablets that is written for health professionals.

For more information, please address medical inquiries to, MedicalAffairs@zydususa.com or Tel.: 1-877-993-8779.

WHAT ARE THE INGREDIENTS OF VARDENAFIL HYDROCHLORIDE TABLETS?

Active Ingredient: vardenafil hydrochloride trihydrate, USP

Inactive Ingredients: colloidal silicon dioxide, hypromellose, iron oxide red (5 mg, 10 mg and 20 mg), iron oxide yellow (5 mg, 10 mg and 20 mg), microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sodium stearyl fumarate, titanium dioxide.

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

Products cited in vardenafil hydrochloride tablets USPI

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