

FDA-approved patient labeling

STAXYN[®] (stax-in) (vardenafil HCl) orally disintegrating tablets

Read the Patient Information about STAXYN 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 STAXYN 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 STAXYN?

STAXYN is not interchangeable with vardenafil film-coated tablets (LEVITRA).

STAXYN 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.

STAXYN contains phenylalanine which can be harmful to people who have phenylketonuria. Talk to your doctor if you have phenylketonuria.

Do not take STAXYN 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 guanylate cyclase stimulator, a medicine that treats pulmonary arterial hypertension and chronic-thromboembolic pulmonary hypertension.

(See “*Who Should Not Take STAXYN?*”)

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

WHAT IS STAXYN?

STAXYN is 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. STAXYN may help a man with ED get and keep an erection when he is sexually excited.

STAXYN does 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.

STAXYN is only for men with ED. STAXYN is not for women or children. STAXYN must be used only under a doctor’s care.

HOW DOES STAXYN 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. STAXYN 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 STAXYN?

Talk to your doctor to decide if STAXYN is right for you.

STAXYN has been shown to be effective in men over the age of 18 years who have erectile dysfunction, including men with diabetes.

WHO SHOULD NOT TAKE STAXYN?

Do not take STAXYN if you:

- **Take any medicines called “nitrates”** (see “*What important information should you know about STAXYN?*”). 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 STAXYN 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 guanylate cyclase stimulator**, a medicine that treats pulmonary arterial hypertension and chronic-thrombotic 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 STAXYN?

Before taking STAXYN, 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.
- Have phenylketonuria.
- Have fructose intolerance.

CAN OTHER MEDICATIONS AFFECT STAXYN?

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. STAXYN 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 STAXYN?*”).
- Medicines that treat abnormal heartbeat. These include quinidine, procainamide, amiodarone and sotalol.
- Ritonavir (Norvir®) or indinavir sulfate (Crixivan®) saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®) or other HIV protease inhibitors.
- Ketoconazole or itraconazole (such as Nizoral® or Sporanox®).
- Erythromycin or clarithromycin.
- Other medicines or treatments for ED.

Patients taking these drugs should not use STAXYN.

Patients taking alpha-blockers should not initiate vardenafil therapy with STAXYN. Patients taking alpha-blockers who have previously used vardenafil film-coated tablets may switch to STAXYN at the advice of their healthcare provider.

- Medicines called alpha-blockers. These include Hytrin® (terazosin HCl), Flomax® (tamsulosin HCl), Cardura® (doxazosin mesylate), Minipress® (prazosin HCl) or Uroxatral® (alfuzosin HCl), Rapaflo® (silodosin). Alpha-blockers are sometimes prescribed for prostate problems or high blood pressure. In some patients the use of PDE5 inhibitor drugs, including STAXYN, with alpha-blockers can lower blood pressure significantly leading to fainting.
- Patients should contact the prescribing physician if alpha-blockers or other drugs that lower blood pressure are prescribed by another healthcare provider.

HOW SHOULD YOU TAKE STAXYN?

Take STAXYN exactly as your doctor prescribes. STAXYN comes in 10 mg orally disintegrating tablets. The dose is one STAXYN tablet. **Do not take more than one STAXYN a day.** Doses should be taken at least 24 hours apart.

- If you have prostate problems or high blood pressure, for which you take medicines called alpha-blockers, you should not start treatment for erectile dysfunction with STAXYN. Your doctor may prescribe a lower dose of vardenafil film-coated tablet.

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

Place on the tongue where it will dissolve rapidly. The tablet should be taken whole and not crushed or split.

The tablet should not be taken with liquid.

It should be taken immediately upon removal from the blister.

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

If you receive STAXYN in a blisterpack, examine the blisterpack before use. Do not use if blisters are torn, broken, or missing.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF STAXYN?

The most common side effects with STAXYN are headache, flushing, stuffy or runny nose, indigestion, upset stomach, dizziness, and 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.

STAXYN 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) 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 STAXYN, 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. 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 STAXYN and contact a doctor right away.

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

HOW SHOULD STAXYN BE STORED?

- Store STAXYN at room temperature between 59–86° F (15–30° C).
- Keep STAXYN and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT STAXYN

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use STAXYN for a condition for which it was not prescribed. Do not give STAXYN 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 STAXYN. If you would like more information, talk with your healthcare provider. You can ask your doctor or pharmacist for information about STAXYN that is written for health professionals.

For more information you can also visit www.STAXYN.com or call 1-888-825-5249.

WHAT ARE THE INGREDIENTS OF STAXYN?

Active Ingredient: vardenafil hydrochloride

Inactive Ingredients of STAXYN: Aspartame, peppermint flavor, magnesium stearate and Pharmaburst™ B2 (crospovidone, mannitol, silica colloidal hydrated, and sorbitol)

Phenylketonurics: STAXYN contains 1.01 mg phenylalanine per tablet.

Products cited in STAXYN USPI

LEVITRA is a registered trademark of Bayer AG and is used under license by GlaxoSmithKline.

Norvir (ritonavir) is a trademark of Abbott Laboratories

Crixivan (indinavir sulfate) is a trademark of Merck & Co., Inc.

Invirase or Fortavase (saquinavir mesylate) is a trademark of Roche Laboratories Inc.

Reyataz (atazanavir sulfate) is a trademark of Bristol-Myers Squibb Company

Nizoral (ketoconazole) is a trademark of Johnson & Johnson

Sporanox (itraconazole) is a trademark of Johnson & Johnson

Hytrin (terazosin HCl) is a trademark of Abbott Laboratories

Flomax (tamsulosin HCl) is a trademark of Yamanouchi Pharmaceutical Co., Ltd.

Cardura (doxazosin mesylate) is a trademark of Pfizer Inc.

Minipress (prazosin HCl) is a trademark of Pfizer Inc.

Rapaflo (silodosin) is a trademark of Watson Pharma Inc.

NDA 200179 Staxyn FDA Approved 16 Sept 2015

Uroxatral (alfuzosin HCl) is a trademark of Sanofi-Synthelabo

Pharmaburst B2 is a trademark of SPI Pharma Inc.

Revision Date 9/2015

Manufactured for:



Bayer HealthCare

Bayer HealthCare Pharmaceuticals Inc.

Whippany, NJ 07981

Manufactured in Germany

Distributed by:



GlaxoSmithKline

GlaxoSmithKline

Research Triangle Park

NC 27709

STAXYN is a registered trademark of Bayer Pharma AG and is used under license by GlaxoSmithKline.

Rx Only

©2010 Bayer HealthCare Pharmaceuticals Inc.