

PART III: CONSUMER INFORMATION

Pr**STAXYN**[®]

(vardenafil orally disintegrating tablets)

IMPORTANT: PLEASE READ

STAXYN[®] is not interchangeable with the film-coated tablet

This leaflet is part III of a three-part "Product Monograph" published when STAXYN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about STAXYN. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

STAXYN is used in the treatment of erectile dysfunction. This is when a man cannot get or keep a hard, erect penis suitable for sexual activity.

What it does:

STAXYN belongs to a class of agents known as phosphodiesterase type 5 (PDE5) inhibitors. Following sexual stimulation, STAXYN works by helping the blood vessels in your penis relax, allowing blood to flow into your penis. This results in improved erectile function.

STAXYN will not increase your sex drive. STAXYN will only help you get an erection if you are sexually stimulated.

When it should not be used:

- If you are taking any medicines containing nitrates in any form. Similarly, nitrates must never be used by men who take STAXYN. Nitrates are found in many prescription medicines used to treat angina (chest pain due to heart disease) such as nitroglycerin, isosorbide mononitrate and isorbide dinitrates. If you do not understand what nitrates are, or are unsure about whether a medication you are on is a "nitrate", ask your doctor or pharmacist.
- If you take STAXYN with nitrate-containing medicines or any other nitrates (eg, amyl nitrite "poppers"), your blood pressure could suddenly drop to a life-threatening level.

You could get dizzy, faint, or even have a heart attack or stroke.

- If you are taking indinavir, ritonavir, ketoconazole, itraconazole, erythromycin, or clarithromycin. Indinavir and ritonavir are used to treat HIV infections. Ketoconazole and itraconazole are used against fungal infections. Erythromycin and clarithromycin are antibiotics.
- If you have ever had an allergic reaction to any of the ingredients in STAXYN. (See **What the medicinal ingredient is** and **What the nonmedicinal ingredients are**.)
- If you have had an episode of vision loss in one or both eyes from a disease called non-arteritic anterior ischaemic optic neuropathy (NAION).
- Do not take STAXYN with guanylate cyclase stimulators, such as riociguat.

What the medicinal ingredient is:

Vardenafil (as vardenafil hydrochloride)

What the nonmedicinal ingredients are:

STAXYN orally disintegrating tablets contain the following nonmedicinal ingredients: aspartame, flavor peppermint, magnesium stearate, and Pharmaburst^{®a} (mannitol, crospovidone, silica colloidal hydrated, sorbitol).

What dosage forms it comes in:

STAXYN is available as white, round, biconvex uncoated tablets without tablet markings. STAXYN is available in one dosage strength: 10 mg, containing 10 mg of the active ingredient vardenafil.

WARNINGS AND PRECAUTIONS

BEFORE you use STAXYN talk to your doctor or pharmacist if you have or had any of the following conditions:

- Heart problems (irregular heartbeats, angina, chest pain, or had a previous heart attack or stroke, QT/QTc prolongation, or a family history of QT/QTc prolongation). If you have heart problems, ask your doctor if your heart is healthy enough to handle the extra strain of having sex.
- An erection that lasted more than 4 hours.
- Low blood pressure.
- Uncontrolled high blood pressure.
- Kidney dialysis.
- Severe liver problems.
- Blood problems, including sickle cell anemia or leukemia.
- Stomach ulcers or any type of bleeding problem.
- Deformation of the penis or Peyronie's disease.

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- Eye disease, or severe loss of vision, including a condition called Nonarteritic Anterior Ischemic Optic Neuropathy (NAION). If you are taking STAXYN and experience temporary or permanent loss or change in vision, stop taking STAXYN and call your doctor.
- Hearing problems or hearing loss. Sudden decrease or loss of hearing has been reported with the use of this class of drug (PDE5 inhibitors), including STAXYN. If you experience these symptoms, stop taking STAXYN and contact your doctor.
- Phenylketonuria. STAXYN contains Aspartame, a source of phenylalanine, and may be harmful for people with phenylketonuria.
- An intolerance to sorbitol. STAXYN contains sorbitol.

STAXYN offers no protection against sexually transmitted diseases including Human Immunodeficiency Virus (HIV).

STAXYN is not recommended for patients less than 18 years old.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with STAXYN include:

- nitrate-containing medicines or nitrates (eg, amyl nitrate “poppers”),
- indinavir or ritonavir (used to treat HIV infections),
- ketoconazole, or itraconazole (used to treat fungal infections),
- gatifloxacin (used to treat infections),
- antiarrhythmic medications (for irregular heartbeat, eg, amiodarone, sotalol, quinidine, procainamide),
- alpha-blockers (used to treat prostate problems or high blood pressure).

Do not consume grapefruit juice while taking STAXYN.

Do not use STAXYN together with other treatments of erectile dysfunction. If you see a different doctor for any reason, be sure to inform him/her that you are taking STAXYN.

PROPER USE OF THIS MEDICATION

- You must take this medicine exactly as prescribed by your doctor.

Usual dose:

- Take one tablet (10 mg) of your STAXYN 45-90 minutes before sexual activity. However, sexual activity can be initiated for up to 8 hours after taking STAXYN.
- Do not take more than 10 mg of STAXYN per day.
- Place STAXYN tablet on the tongue, where it will dissolve in seconds, then swallow with saliva. STAXYN tablets should be taken without any liquid.
- Do not remove the orally disintegrating tablet from the blister until you are going to take it. With dry hands, pull the blister edge from the blister holder and press gently on

top to release the tablet on your hand. Do not crush the tablet.

- STAXYN can be taken before or after food.
- STAXYN is not affected by moderate amounts of alcohol (approximately 2 drinks of alcohol, wine, or beer in a 70 kg person). However, large amounts of alcohol can impair the ability to get an erection; therefore do not consume large amounts of alcohol prior to sexual activity.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Overdose:

If you have taken more STAXYN than you should, contact your doctor or a Poison Control Centre immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, STAXYN can cause some side-effects.

The most common side-effects are headache and flushing (a burning/warm sensation, usually in the face).

The common side-effects are indigestion, stuffy nose, dizziness, and back pain.

Less common side effects are sudden decrease or loss of hearing and transient global amnesia (temporary memory loss). A small percentage of patients could experience abnormal vision (eg, decreased and blurred vision, increased perception to light, changes in blue/green colour discrimination). If this happens to you, do not operate a motor vehicle or any heavy machinery until the adverse effects disappear.

If you have any of these adverse effects and they are severe or do not disappear, talk to your doctor or pharmacist.

- If you have an erection which lasts longer than 4 hours, you should contact a doctor immediately. If this is not treated immediately, permanent penile tissue damage and erectile dysfunction may result.
- If you have a heart condition and you experience any symptoms of a heart attack upon starting sexual activity (such as chest pains, irregular heartbeat, or shortness of breath), you should stop this activity and consult a doctor.
- If an allergic reaction occurs after taking STAXYN, such as a rash, itching, swollen face, lips, throat, or shortness of breath, contact a doctor immediately.

Sudden decrease or loss of vision has occurred rarely after the use of oral erectile dysfunction medications, including STAXYN. It has not been established whether the loss of vision is related directly to the use of PDE5 inhibitors or other factors. If you experience reduction or loss of vision in one or both eyes, stop taking STAXYN and call your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Rare (<0.1%)			
• Priapism/erection lasting longer than 4 hours			✓
• Symptoms of a heart attack upon starting sexual activity/chest pain, irregular heartbeat, shortness of breath			✓
• Allergic reaction/rash, itching, swollen face, lips, throat, shortness or breath			✓

This is not a complete list of side effects. For any unexpected effects while taking STAXYN, contact your doctor or pharmacist.

HOW TO STORE IT

STAXYN should be stored between 15°C to 30°C in the original package. Do not freeze.

Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and email address.

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Last revised: July 22, 2016

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