

PART III: CONSUMER INFORMATION

Pr MYLAN-VARDENAFIL

Vardenafil tablets

This leaflet is part III of a three-part "Product Monograph" published when Mylan-Vardenafil was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Mylan-Vardenafil. 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:

MYLAN-VARDENAFIL 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:

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

MYLAN-VARDENAFIL will not increase your sex drive. MYLAN-VARDENAFIL 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 MYLAN-VARDENAFIL. 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 MYLAN-VARDENAFIL 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 cobicistat, indinavir, ritonavir, saquinavir, atazanavir, ketoconazole, or itraconazole. Cobicistat, indinavir, ritonavir, saquinavir and atazanavir are used to treat HIV infections. Ketoconazole and itraconazole are used against fungal infections.
- If you have ever had an allergic reaction to any of the ingredients in MYLAN-VARDENAFIL. (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 MYLAN-VARDENAFIL with guanylate cyclase stimulators, such as riociguat.

What the medicinal ingredient is:

Vardenafil (as vardenafil hydrochloride trihydrate)

What the nonmedicinal ingredients are:

Cellulose microcrystalline, crospovidone, silica (colloidal anhydrous), magnesium stearate. The coating contains: hypromellose, titanium dioxide, macrogol, iron oxide yellow and iron oxide red.

What dosage forms it comes in:

Mylan-Vardenafil is available as Tablets

Each tablet contains 5 mg, 10 mg or 20 mg of Vardenafil which is equivalent to 5.926 mg, 11.853 mg or 23.705 mg of vardenafil hydrochloride trihydrate, respectively. Mylan-Vardenafil 5 mg, 10 mg and 20 mg are brown, film-coated, round, biconvex, beveled edge tablet debossed with VL on one side of the tablet and M5, M over 10 and M over 20 respectively on the other side.

WARNINGS AND PRECAUTIONS

BEFORE you use MYLAN-VARDENAFIL 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). If you have heart problems, ask your doctor if your heart is healthy enough to handle the extra strain of having sex.
- 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, Peyronie's disease or an erection that lasted more than 4 hours.
- If you are taking MYLAN-VARDENAFIL and experience temporary or permanent loss or change in

vision, stop taking MYLAN-VARDENAFIL and call your doctor.

- Severe loss of vision due to damage to the optic nerve from insufficient blood supply, a condition called Non-arteritic Anterior Ischemic Optic Neuropathy (NAION). If you are taking MYLAN-VARDENAFIL and experience temporary or permanent loss or change in vision, stop taking MYLAN-VARDENAFIL and call your doctor.
- A rare, inherited eye disease called retinosa pigmentosa.

MYLAN-VARDENAFIL offers no protection against sexually transmitted diseases including Human Immunodeficiency Virus (HIV).

MYLAN-VARDENAFIL is not recommended for patients less than 18 years old.

Sudden decrease or loss of hearing has been reported in a few post-marketing and clinical trial cases with the use of PDE5 inhibitors, including MYLAN-VARDENAFIL. It has not been established whether these are related directly to the use of these medications or to other factors. If you experience these symptoms, stop taking MYLAN-VARDENAFIL and call your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MYLAN-VARDENAFIL include:

- nitrate-containing medicines or nitrates (eg, amyl nitrate “poppers”),
- cobicistat, indinavir, ritonavir, saquinavir, or atazanavir (used to treat HIV infections),
- ketoconazole, or itraconazole (used to treat fungal infections),
- erythromycin, clarithromycin, or 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).
- riociguat (medicine used to treat high blood pressure in the arteries carrying blood from the heart to the lungs). Taking this medicine with vardenafil could seriously affect your blood pressure (see “**When it should not be used**”).

MYLAN-VARDENAFIL might increase the amount of some medicines in your blood (sensitive P-gp substrates). Dabigatran (used to prevent blood clots from forming) is an example of these medicines.

Do not consume grapefruit juice while taking MYLAN-VARDENAFIL.

MYLAN-VARDENAFIL should not be used together with other treatments of erectile dysfunction.

PROPER USE OF THIS MEDICATION

Usual dose:

- You must take this medicine exactly as prescribed by your doctor.
- Take your MYLAN-VARDENAFIL 25-60 minutes before sexual activity. However, sexual activity can be initiated as soon as 15 minutes and as long as 8-10 hours after taking MYLAN-VARDENAFIL.
- MYLAN-VARDENAFIL will only help you get an erection if you are sexually stimulated.
- MYLAN-VARDENAFIL tablets should be swallowed whole with some water. It does not matter if you take MYLAN-VARDENAFIL with or without food.
- MYLAN-VARDENAFIL 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.
- You should not take more than one dose of MYLAN-VARDENAFIL per day.
- Never change the dose unless your doctor tells you to.
- If you have to see a different doctor for any reason, be sure to inform him/her that you are taking MYLAN-VARDENAFIL.

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 think you have taken too much MYLAN-VARDENAFIL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, MYLAN-VARDENAFIL can cause some side-effects. These effects are usually mild to moderate in nature and do not last for a long time.

The most common side-effects are headache and flushing (a burning/warm sensation, usually in the face). Less commonly reported side-effects are indigestion, stuffy nose, 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) after taking MYLAN-VARDENAFIL. 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 MYLAN-VARDENAFIL, such as a rash, itching, swollen face, lips, throat, or shortness of breath, stop use and contact a doctor.

Sudden decrease or loss of vision has occurred rarely after the use of oral erectile dysfunction medications, including MYLAN-VARDENAFIL. It has not been established whether the loss of vision is related directly to the use of PDE5 inhibitors or other factors. People who have previously experienced a type of vision loss called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) may be at an increased risk of reoccurrence of NAION. If you experience reduction or loss of vision in one or both eyes, stop taking MYLAN-VARDENAFIL and call your doctor.

Keep out of the reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about MYLAN-VARDENAFIL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by calling 1-844-596-9526

This document can be found at: www.mylan.ca.

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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 seek immediate emergency medical attention
	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 of breath			✓

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

HOW TO STORE IT

Store MYLAN-VARDENAFIL between 15°C to 30°C. Do not freeze.