

PART III: CONSUMER INFORMATION

**PrMYLAN-TADALAFIL
Tadalafil Tablets, USP
2.5 mg, 5 mg, 10 mg, 20 mg**

This leaflet is part III of a three-part "Product Monograph" published when MYLAN-TADALAFIL 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-TADALAFIL. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet 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 your pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

MYLAN-TADALAFIL is used for treatment of

- erectile dysfunction (ED) in men (when a man cannot get, or keep a hard, erect penis suitable for sexual activity).
- the signs and symptoms of benign prostatic hyperplasia (BPH). These symptoms include a frequent need to urinate, a sensation of not emptying the bladder completely, or painful urination.
- both ED and the signs and symptoms of BPH.

What it does:

MYLAN-TADALAFIL belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Treatment of ED: Following sexual stimulation MYLAN-TADALAFIL works by helping the blood vessels in your penis to relax, allowing the flow of blood into your penis. This results in improved erectile function.

It is important to note that MYLAN-TADALAFIL works only with sexual stimulation. MYLAN-TADALAFIL alone does not increase sexual desire.

Treatment of BPH and ED/BPH: MYLAN-TADALAFIL works by relaxing muscles in the prostate and bladder, which may reduce BPH symptoms.

When it should not be used:

Do not take MYLAN-TADALAFIL:

- If you are taking any medicines that contain nitrates in any form (oral, sublingual [under the tongue], skin-patch, or by inhalation). Similarly, nitrates must never be used by men who take MYLAN-TADALAFIL. Nitrates are found in many prescription medicines used in the treatment of angina pectoris (chest pain due to heart disease), such as nitroglycerin, isosorbide mononitrate, or isosorbide dinitrate. If nitrates have previously been prescribed to you, even though you may not have used them, or are unsure, tell your doctor.

If you take MYLAN-TADALAFIL with any nitrate-containing medicines or any other nitrates (e.g., 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.

- Do not take MYLAN-TADALAFIL if you have had an allergic reaction in the past to tadalafil or any of the other ingredients in MYLAN-TADALAFIL listed below.
- If you have had a previous episode of an eye condition called NAION which causes a sudden decrease or loss of vision in one or both eyes.
- If you are taking **riociguat (ADEMPAS®)**

What the medicinal ingredient is:

Tadalafil

What the nonmedicinal ingredients are:

Acetone (trace amount), croscarmellose sodium, dimethyl sulphoxide (trace amount), hypromellose, iron oxide yellow, lactose anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer, povidone, silica colloidal anhydrous, sodium laurilsulfate, titanium dioxide, and triacetin. MYLAN-TADALAFIL 2.5 mg also contains talc and iron oxide red, MYLAN-TADALAFIL 5 mg also contains talc, MYLAN-TADALAFIL 10 mg and 20 mg contain iron oxide black.

What dosage forms it comes in:

MYLAN-TADALAFIL comes as yellow or yellow-orange film-coated tablets. They are almond shaped, biconvex and have an “M” on one side and “TL5”(2.5mg tablets), “TL6”(5mg tablets), “TL7”(10mg tablets), or “TL8”(20mg tablets) on the other side. The active substance is tadalafil. Each tablet of MYLAN-TADALAFIL contains 2.5 mg, 5 mg, 10 mg or 20 mg of tadalafil.

WARNINGS AND PRECAUTIONS

Before taking MYLAN-TADALAFIL talk to your doctor if you: have or had any of the following conditions:

- Heart disease or previously had a heart attack: Sexual

activity carries a possible risk to patients with heart disease because it puts extra strain on your heart. Before you start any treatment for erectile dysfunction, ask your doctor if your heart is healthy enough to handle the extra strain of having sex. If you have chest pains, dizziness or nausea during sex, stop exerting yourself and tell your doctor you have had this problem.

- Stroke.
- Low blood pressure or uncontrolled high blood pressure.
- Liver or kidney problem.
- Sickle cell anemia (an abnormality of red blood cells), multiple myeloma (cancer of the bone marrow), or leukemia (cancer of the blood cells).
- Peptic ulcer or other bleeding disorders.
- Deformation of the penis.
- Ever had severe loss of vision, including a condition called Non-Arteritic Ischemic Optic Neuropathy (NAION). The specific type of vision decrease or loss known as NAION has been reported rarely after the intake of tadalafil or other PDE5 inhibitors. Vision decrease or loss may be partial or complete, in one or very occasionally in both eyes. While in some cases the condition may improve over time, it can also be irreversible. If you are taking MYLAN-TADALAFIL and experience temporary or permanent loss or change in vision, stop taking MYLAN-TADALAFIL and immediately call your doctor.
- Hearing problems: Sudden decrease or loss of hearing has been reported with the use of PDE5 inhibitors, including tadalafil, although it is not known if it is due to drug or other factors.
- Lactose or milk sugar intolerance. MYLAN-TADALAFIL contains a small amount of lactose

MYLAN-TADALAFIL is not recommended to be used in combination with alpha blockers if you have symptoms of BPH.

MYLAN-TADALAFIL does not protect against sexually transmitted diseases including HIV/ AIDS.

Long-term studies have shown that tadalafil therapy may decrease sperm concentration in some men. The effect on fertility in men is unknown.

MYLAN-TADALAFIL is not intended for use by women or by children under 18 years of age.

When tadalafil is used for the treatment of erectile dysfunction,

diarrhea was reported more frequently in patients 65 years of age and older (2.5% of patients).

Only your doctor can decide if MYLAN-TADALAFIL is right for you. If you have ED, you will need to have a physical examination to diagnose your erectile dysfunction and to find out if you can take MYLAN-TADALAFIL alone or with your other medicines. If you have urinary problems, you will need to have a physical examination to diagnose your BPH and not a more serious condition such as prostate cancer.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including the medicine you can buy without prescription and natural health products.

Drugs that may interact with MYLAN-TADALAFIL include:

- nitrates (see previous section)
- rifampin (an antibacterial product used against tuberculosis)
- ketoconazole or itraconazole (used against fungal infections)
- erythromycin (an antibacterial product)
- protease inhibitors such as ritonavir and saquinavir (HIV treatments)

You should not use MYLAN-TADALAFIL together with any other treatments for erectile dysfunction or PDE5 inhibitors for treatment of pulmonary arterial hypertension (PAH), such as ADCIRCA® (tadalafil) or REVATIO® (sildenafil).

Tell your doctor if you are taking:

- medicines to treat high blood pressure
- alpha-blockers (such as doxazosin) for the treatment of prostate problems.

The combination of these medicines with MYLAN-TADALAFIL may add to the blood-pressure-lowering effect of these drugs.

PROPER USE OF THIS MEDICATION

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.

How To Take MYLAN-TADALAFIL:

Always take MYLAN-TADALAFIL exactly as your doctor has

instructed you. You should check with your doctor or pharmacist if you are unsure. Do not take a higher dose than the one which your doctor prescribed for you.

MYLAN-TADALAFIL tablets are for oral use. Swallow the tablet whole, with some water.

You may take MYLAN-TADALAFIL with or without food.

Alcohol consumption may decrease the ability to attain an erection and may also temporarily decrease blood pressure.

There are two different ways of taking MYLAN-TADALAFIL tablets to treat ED: a 20 mg on-demand dose taken as needed, or a lower 5 mg daily dose. It may take up to up 5 days for MYLAN-TADALAFIL *once-a-day* to reach steady blood levels.

For patients with ED:

- Try sex at different times to find out what works best for you and your partner.
- MYLAN-TADALAFIL works only if you are sexually stimulated.
- If you don't get the results you expect — talk to your doctor or pharmacist.

MYLAN-TADALAFIL for “On-Demand” Dosing: The recommended dose is one tablet (20 mg) before sexual activity, as needed. You should NOT take more than the prescribed dose of one MYLAN-TADALAFIL 10 mg or 20 mg tablet per day. The 10 mg and 20 mg doses are not recommended for continuous daily use.

You can engage in sexual activity within 30 minutes of taking the tablet and up to 36 hours later. The amount of time MYLAN-TADALAFIL takes to work varies from person to person.

MYLAN-TADALAFIL for *once-a-day* Use:

Treatment of ED: Your doctor may recommend that you take one tablet of MYLAN-TADALAFIL (5 mg or 2.5 mg) *once-a-day* every day, at approximately the same time each day, regardless of when you are planning to have sex.

Treatment of BPH and ED/BPH: Your doctor may recommend that you take one tablet of MYLAN-TADALAFIL 5 mg *once-a-day* every day, at approximately the same time each day.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MYLAN-TADALAFIL can have some side-effects. These effects are usually mild to moderate in nature.

The most common side effects are headache, indigestion, back pain, muscle aches, nasal congestion, facial flushing, dizziness and high blood pressure.

Uncommon side-effects: swelling of the eyelids, eye pain, conjunctival hyperemia (red eyes) and allergic reactions (including skin rashes).

Rarely, a prolonged and possibly painful erection may occur after taking MYLAN-TADALAFIL. **If you have such an erection which lasts continuously for more than 4 hours, you should contact a doctor immediately. If this is not treated immediately, permanent penile tissue damage and erectile dysfunction may result.**

Sudden decrease or loss of vision has occurred rarely after the use of oral erectile dysfunction medications, including tadalafil. People who have previously experienced a type of vision loss called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) are at an increased risk of reoccurrence of NAION. If you experience reduction or loss of vision in one or both eyes, stop taking MYLAN-TADALAFIL and immediately call your doctor.

If you take MYLAN-TADALAFIL and have chest pain during or after sexual activity, DO NOT use nitrates, and seek immediate medical assistance.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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	
<u>Common</u> headache indigestion back pain muscle aches nasal congestion facial flushing	✓ ✓ ✓ ✓ ✓ ✓		
<u>Uncommon</u> Swelling of eyelids eye pain red eyes dizziness allergic reaction	✓ ✓ ✓ ✓	✓	
<u>Rare</u> prolonged erection chest pain vision loss hearing loss transient amnesia			✓ ✓ ✓ ✓ ✓

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

HOW TO STORE IT

Store MYLAN-TADALAFIL between 15°C and 30°C.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9
 Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect. (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>)

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

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

The full Product Monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-800-575-1379

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