PART III: CONSUMER INFORMATION

PrLEVITRA®

(vardenafil tablets)

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

LEVITRA 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:

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

LEVITRA will not increase your sex drive. LEVITRA 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 LEVITRA. 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 LEVITRA 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, or itraconazole. Indinavir and ritonavir 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 LEVITRA. (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 LEVITRA with guanylate cyclase stimulators, such as riociguat.

What the medicinal ingredient is:

Vardenafil (as vardenafil hydrochloride)

What the nonmedicinal ingredients are:

The tablets contain the following non-medicinal ingredients: microcrystalline cellulose, crospovidone, anhydrous colloidal silica, magnesium stearate, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, yellow ferric oxide, and red ferric oxide.

What dosage forms it comes in:

LEVITRA is available as orange, round tablets with the BAYER cross on one side, and "5", "10" or "20" on the other. LEVITRA is available in 3 dosage strengths: 5 mg, 10 mg, and 20 mg, containing 5 mg, 10 mg, or 20 mg of the active ingredient vardenafil.

WARNINGS AND PRECAUTIONS

BEFORE you use LEVITRA 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 you 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 LEVITRA and experience temporary or permanent loss or change in vision, stop taking LEVITRA and call your doctor.

- Severe loss of vision, including a condition called Non-arteritic Anterior Ischemic Optic Neuropathy (NAION).
- A rare, inherited eye disease called retinosa pigmentosa.

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

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

Sudden decrease or loss of hearing has been reported in a few postmarketing and clinical trial cases with the use of PDE5 inhibitors, including LEVITRA. 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 LEVITRA and call your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with LEVITRA 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),
- 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).

Do not consume grapefruit juice while taking LEVITRA.

LEVITRA 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 LEVITRA 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 LEVITRA.
- LEVITRA will only help you get an erection if you are sexually stimulated.
- LEVITRA tablets should be swallowed whole with some water. It does not matter if you take LEVITRA with or without food.
- LEVITRA 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 LEVITRA 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 LEVITRA.

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 LEVITRA than you should, contact your doctor or a Poison Control Centre immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, LEVITRA 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 LEVITRA. 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 LEVITRA, 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 LEVITRA. 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 LEVITRA 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 LEVITRA, contact your doctor or pharmacist.

HOW TO STORE IT

LEVITRA should be stored between 15-30°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 1 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 Report Form and:
  - Fax toll free to 1-866-678-6789
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

REPORTING SUSPECTED SIDE EFFECTS

Postage paid labels, Canada Vigilance Report Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website 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 e-mail address.

This leaflet was prepared by:

Bayer Inc.
2920 Matheson Boulevard East
Mississauga, Ontario
L4W 5R6
Canada

Last revised: June 4, 2015

Bayer