

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr**VIAGRA**<sup>®</sup>**

##### **Sildenafil tablets**

##### **Sildenafil orodispersible films**

Read this carefully before you start taking **VIAGRA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIAGRA**.

#### **What is VIAGRA used for?**

VIAGRA is used to treat erectile dysfunction in male adults. Erectile dysfunction is the inability to get or keep an erected penis that is hard enough for sex.

VIAGRA works only with sexual stimulation. VIAGRA alone does not increase your sex drive.

#### **How does VIAGRA work?**

VIAGRA works by helping to relax the blood vessels in your penis after being sexually aroused. This allows blood to flow into your penis. This results in improved erectile function.

#### **What are the ingredients in VIAGRA?**

Medicinal ingredients: sildenafil (as sildenafil citrate)

Non-medicinal ingredients:

Tablets: anhydrous dibasic calcium phosphate, croscarmellose sodium, FD & C Blue #2 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin.

Orodispersible film: crospovidone, hydroxypropyl cellulose, hypromellose, levomenthol, macrogol 400, macrogol polyvinyl alcohol grafted copolymer, povidone, red ferric oxide, sucralose, titanium dioxide.

#### **VIAGRA comes in the following dosage forms:**

- Tablets: 25 mg, 50 mg or 100 mg sildenafil (as sildenafil citrate).
- Orodispersible films: 50 mg sildenafil (as sildenafil citrate).

#### **Do not use VIAGRA if:**

- You are taking any medicines containing nitrates in any form (oral, sublingual [under the tongue], skin patch, or by inhalation [spray]).
  - Never take nitrates after using VIAGRA even if you have chest pain. 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 do not understand what nitrates are, or are unsure about whether a medication you are taking is a “nitrate”, ask your healthcare professional.
- You have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION).
- You have ever had an allergic reaction to sildenafil or any other ingredients in VIAGRA.
- You are not supposed to have sexual activity because of your overall health condition.
- You are taking medication for pulmonary hypertension (guanylate cyclase stimulators), such as riociguat.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIAGRA. Talk about any health conditions or problems you may have, including if you:**

- have heart problems (like irregular heart beats, heart failure, heart disease, heart attack, angina, chest pain).
  - ask your healthcare professional if your heart is healthy enough to handle the extra strain of having sex. If you have chest pain, dizziness or nausea during sex, stop exerting yourself. Do **not** use nitrates but you should get medical help right away.
- are 65 years of age or over
- have had a stroke
- have low blood pressure or uncontrolled high blood pressure
- have liver or kidney problems
- have sickle cell anemia (abnormality of the red blood cells), multiple myeloma (cancer of the bone marrow) or leukaemia (cancer of the white blood cells)
- have a deformed penis or other penis problems
- have ever had an erection that lasted more than 4 hours
- have stomach ulcers or other bleeding problems
- have an eye disease called retinitis pigmentosa

**Other warnings you should know about:**

**Eye Problems:** VIAGRA may cause a sudden decrease or loss of vision. If this happens, stop taking VIAGRA and tell your healthcare professional right away.

**Ear Problems:** VIAGRA may cause sudden decrease or loss of hearing, dizziness or ringing in the ears. If you experience these symptoms, stop taking VIAGRA and talk to your healthcare professional.

**Driving and using machines:** Before you perform tasks which may require special attention, wait until you know how you respond to VIAGRA. Dizziness or altered vision (colour, light

sensitivity, blurry vision, eye pain, red eyes) can occur while using VIAGRA.

**Sexual Health:**

- VIAGRA does not protect against sexually transmitted diseases (STD), including Human Immunodeficiency Virus (HIV).
- Tell your healthcare professional right away if you have an erection that lasts longer than 4 hours.
- Drinking alcohol may decrease the ability to get an erection.

**Women and children:** VIAGRA is not for use in women and children under 18 years of age.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**Serious Drug Interactions**

Serious drug interactions with VIAGRA include:

- Any medicines that contain nitrates, used to treat chest pain due to heart disease
- Guanylate cyclase stimulators, used to treat pulmonary hypertension, such as riociguat.

**The following may interact with VIAGRA:**

- Medicines used to treat prostate problems or high blood pressure (alpha-blockers), such as doxazosin
- Medicines used to treat fungal infections, such as ketoconazole, itraconazole
- Medicines used to treat bacterial infections, such as erythromycin, rifampin
- Medicines used to treat HIV, such as ritonavir, saquinavir
- Medicines used to treat high blood pressure in the blood vessels between the heart and the lungs, like bosentan and other medicines that contain sildenafil
- Cimetidine, a medicine used to treat stomach or digestive problems
- Other medicines used to treat erectile dysfunction
- Grapefruit juice may increase the levels of VIAGRA in your blood
- High fat meals may delay the effect of VIAGRA

## How to take VIAGRA:

### Tablets and Orodispersible films:

- Always take VIAGRA as directed by your healthcare professional. Talk to your healthcare professional if you are unsure.
- Take VIAGRA about 30 to 60 minutes before sexual activity. You may take VIAGRA between 30 minutes to 4 hours before sexual activity if needed.
  - The amount of time it takes to have an effect varies slightly from person to person. Sexual stimulation is needed for VIAGRA to work.
- Take with or without food. However, VIAGRA may take longer to work if you take it with a high-fat meal.

### Tablets:

- Swallow tablet whole with some water.

### Orodispersible films:

- Place the film on your tongue with a dry finger. Allow the film to dissolve completely before swallowing with or without water.
- You can swallow your saliva while the film is dissolving, without swallowing the film.
- If a second film is needed for a 100 mg dose, take the second film once the first is fully dissolved.

### Recommended dose:

- **Tablets:** Your healthcare professional can determine the dose that works best for you.
- **Orodispersible films:** 1 - 2 films (50 mg to 100 mg) per dose, per day.

The maximum dose is 100 mg per day. You should not take more than one dose of VIAGRA per day.

If you have serious liver or kidney problems or you are 65 years of age or over, your healthcare professional may start you at the lowest dose of VIAGRA.

### Overdose:

If you think you, or a person you are caring for, have taken too much VIAGRA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### What are possible side effects from using VIAGRA?

These are not all the possible side effects you may have when taking VIAGRA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- headache, facial flushing
- nausea, vomiting, indigestion, abdominal pain, diarrhea

- dizziness
- dry, stuffy, or swollen nose
- throat tightness, dry mouth, decreased sensitivity of the mouth
- pain in arms and legs, myalgia (muscle pain), back pain
- sleepiness/drowsiness
- cold or flu symptoms
- erection increased

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>LESS COMMON</b>			
<b>Ear problems:</b> sudden decrease or loss of hearing, ringing in the ears		✓	
<b>Eye problems:</b> colour tinge, blurred vision, loss of vision in eye, increased sensitivity of the eyes to light, eye pain or redness, swelling and itching of the eyelids, decreased sharpness of vision, eye irritation, blocked eye veins, eye pressure			✓
<b>RARE</b>			
<b>Serious skin reactions:</b> redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			✓
<b>VERY RARE</b>			
<b>Priapism:</b> erection lasting more than 4 hours			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b>			
<b>Allergic reactions:</b> rash, hives, itch, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
<b>Arrhythmia / tachycardia</b> (abnormal heart rhythms): fast or irregular heart beat, palpitations, heart rate increased, shortness of breath, dizziness			✓
<b>Chest pain</b>			✓
<b>Cough</b>		✓	
<b>Fever</b>		✓	
<b>Hypotension</b> (low blood pressure): dizziness, fainting, lightheadedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		
<b>Myocardial infarction</b> (heart attack): chest pain or pressure, shortness of breath, jaw, left arm, between the shoulder blades or upper abdomen, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			✓
<b>Nosebleeds</b>		✓	
<b>Pulmonary Hemorrhage</b> (acute bleeding from the lung): oozing of bloody fluid from the nose and respiratory tract, accompanied by rapid worsening of patient respiration, turning blue and in severe cases, shock)			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Seizures:</b> uncontrollable shaking with or without loss of consciousness			✓
<b>Shortness of breath</b>		✓	
<b>Stroke</b> (bleeding in the brain): bleeding in the brain, vision changes, difficulty speaking, weakness on one side of the body, dizziness, lack of coordination or poor balance			✓
<b>Transient global amnesia</b> (temporary memory loss)		✓	
<b>Transient ischaemic attack:</b> temporary loss of vision, difficulty speaking, weakness on one side of the body, numbness or tingling usually on one side of the body, dizziness, lack of coordination or poor balance.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### 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.*

**Storage:**

- Store between 15°C and 30°C, in the original package.
- Do not take VIAGRA after the expiry date shown on the package.
- Always keep VIAGRA out of reach and sight of children.

**If you want more information about VIAGRA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.viatris.ca](http://www.viatris.ca), or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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