

PART III: CONSUMER INFORMATION

PrSILDENAFIL

Sildenafil tablets (as sildenafil citrate)

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

ABOUT THIS MEDICATION

What the medication is used for:

SILDENAFIL (sildenafil citrate) is a treatment for erectile dysfunction in male adults. This is when a man cannot achieve or maintain a hard, erected penis for satisfactory sexual activity.

It is important to note **that SILDENAFIL works only with sexual stimulation**. SILDENAFIL alone does not increase your sex drive.

What it does:

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

When it should not be used:

- If you are taking any medicines containing nitrates in any form (oral, sublingual [under the tongue], skin patch, or by inhalation [spray]). Although SILDENAFIL is used occasionally, nitrates must never be used. Nitrates are found in many prescription medicines that are used in the treatment of angina pectoris (chest pain due to heart disease), such as nitroglycerin, isosorbide mononitrate, or isosorbide dinitrate. If you do not understand what nitrates are, or are unsure about whether a medication you are taking is a "nitrate", ask your doctor or pharmacist.

If you take SILDENAFIL with 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.

- If you have loss of vision in one or both eyes from an eye disease called Non-Arteritic Anterior Ischaemic Optic Neuropathy (NAION).
- If you have ever had an allergic reaction to sildenafil citrate or the non-medicinal ingredients in SILDENAFIL.
- SILDENAFIL is not to be used in men for whom sexual activity is inadvisable.

- Do not take SILDENAFIL with guanylate cyclase stimulators, such as riociguat.

What the medicinal ingredient is:

sildenafil citrate.

What the non-medicinal ingredients are:

Colloidal Silicon Dioxide, Corn Starch, FD&C Blue #2/Indigo Carmine Aluminum Lake, Hypromellose, Lactose, Magnesium Stearate, Polyethylene Glycol, Povidone, Sodium Lauryl Sulphate, Sodium Starch Glycolate, and Titanium Dioxide.

What dosage forms it comes in:

Tablets: 25 mg, 50 mg, and 100 mg

WARNINGS AND PRECAUTIONS

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.

BEFORE you use SILDENAFIL talk to your doctor or pharmacist if you:

- have heart problems (irregular heartbeats, angina, chest pain, or had a heart attack). If you have heart problems, ask your doctor 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. You should **not** use nitrates but you should seek immediate medical assistance.
- 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)
- are allergic to sildenafil or any of the other ingredients of SILDENAFIL tablets
- have a deformed penis or Peyronie's disease
- have ever had an erection that lasted more than 4 hours
- have stomach ulcers or other bleeding problems.
- have a rare inherited eye disease called retinitis pigmentosa
- have had temporary, decrease, or permanent loss of vision in one or both eyes, including a condition called Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION). The specific type of vision decrease or loss, called Non-Arteritic Anterior Ischaemic Optic Neuropathy (NAION), seems to occur rarely when blood flow to the optic nerve is reduced or blocked. Vision decrease or loss may be partial or complete, in one or very occasionally both eyes. While in some cases

IMPORTANT: PLEASE READ

the condition may improve over time, it can also be irreversible.

- rare, but serious skin reactions of Stevens-Johnson's Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported during the post-marketing period.

SILDENAFIL is not recommended for use in children under 18 years of age and in women.

SILDENAFIL does not protect against sexually transmitted diseases (STD), including Human Immunodeficiency Virus (HIV).

Alcohol consumption may decrease the ability to get an erection.

Patients should know how to react to the drug before operating a motor vehicle or any machinery.

If you are taking SILDENAFIL and experience temporary, decrease, or permanent loss of vision, stop taking SILDENAFIL and call your doctor.

In case of chest pain occurring during or after sexual activity you should not use nitrates but you should seek immediate medical assistance.

Sudden decrease or loss of hearing has been reported in a few number of post-marketing and clinical trial cases with the use of PDE5 inhibitors, including SILDENAFIL. 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 SILDENAFIL and call your doctor.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to SILDENAFIL. Dizziness or altered vision can occur while using SILDENAFIL.

INTERACTIONS WITH THIS MEDICATION

You should tell your doctor or pharmacist about any other medications that you are taking. SILDENAFIL may interfere with some drugs. Only take SILDENAFIL with other drugs if recommended by your doctor.

Drugs that may interact with SILDENAFIL include:

- any drugs that contain nitrates in any form (oral, sublingual [under the tongue], skin patch or by inhalation [spray]). Nitrates are found in many prescriptions that are used to treat angina pectoris (chest pain due to heart disease). You should not take SILDENAFIL if you are taking these drugs.
- alpha-blockers (drugs used to treat prostate problems or high blood pressure)
- ketoconazole or itraconazole (drugs used to treat fungal infections)
- erythromycin (a drug used to treat bacterial infections)
- ritonavir, saquinavir or other drugs for the treatment of HIV

- cimetidine (a drug generally used to treat duodenal or gastric problems)
- bosentan (a drug used in the treatment of high blood pressure in the blood vessels between the heart and the lungs)
- drugs used to treat erectile dysfunction. These drugs are tadalafil and vardenafil.
- other drugs that contain sildenafil. They are used in the treatment of high blood pressure in the blood vessels between the heart and the lungs.

Grapefruit juice may increase the levels of SILDENAFIL in your blood.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor can determine the dose that works best for you. Always take SILDENAFIL as prescribed by your doctor. You should speak with your doctor or pharmacist if you are unsure. A dose above 100 mg per day is not recommended.

Swallow the tablet whole, with some water.

You should **not** take more than one dose of SILDENAFIL per day.

If you have serious liver or kidney problems or you are 65 years of age or over, your doctor may start you at the lowest dose (25 mg) of SILDENAFIL.

How to optimize your use of SILDENAFIL:

You should take SILDENAFIL approximately 30 to 60 minutes before sexual activity. You can engage in sexual activity within 30 minutes of taking the tablet and for up to 4 hours. The amount of time it takes to have an effect varies slightly from person to person. Remember, sexual stimulation is required for SILDENAFIL to work.

You should avoid excessive drinking of alcohol, since alcohol can temporarily impair the ability to get an erection.

SILDENAFIL can be taken with or without food. However, you may find that it takes longer for SILDENAFIL to work if you take it with a high-fat meal.

SILDENAFIL may not work the first time or every time. If SILDENAFIL did not work for you on one occasion, try again on another day. You will learn how well SILDENAFIL works for you through your personal experience. The first few times may be charged with emotion or anxiety. If after a few separate attempts, you do not get the results you expect, talk to your doctor.

Overdose:

If you think you have taken too much SILDENAFIL, 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, SILDENAFIL can cause some side effects. These effects are usually mild to moderate in nature and do not last for a long time.

Side effects may include:

- headache, facial flushing
- nausea, vomiting, indigestion, abdominal pain,
- dizziness
- dry, stuffy, or swollen nose
- throat tightness, dry mouth, decreased sensitivity of the mouth
- pain in arms and legs, myalgia (muscle pain)
- somnolence
- erection increased

If you notice any side effects not mentioned above, or any of the above-mentioned side effects persist or become bothersome, please contact 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	
Less common	Effect on hearing: sudden decrease or loss of hearing		✓	
	Effects on vision: colour tinge, increased brightness of light, blurred vision			✓
	Impaired or sudden loss of vision: decreased eyesight or unable to see with one or both eyes			✓
	Detached retina: a decrease in, or sudden loss of vision in one or both eyes			✓

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	Serious skin reactions: rash, blisters, peeling skin and pains.			✓
Very Rare	Priapism: erection lasting more than 4 hours			✓
Unknown	Cough		✓	
	Allergic reactions: rash, hives, itch, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Nosebleed		✓	
	<i>Noted in patients taking sildenafil citrate for pulmonary hypertension:</i> Fever		✓	
Unknown	Shortness of breath		✓	
	Seizure, seizure recurrence			✓
	Transient global amnesia: temporary memory loss		✓	
	Heart attack (myocardial infarction): chest pain, shortness of breath			✓
	Chest pain (unstable angina)			✓
	Arrhythmia/tachycardia, palpitations: fast or irregular heartbeat, heart rate increased			✓
	Hypotension (low blood pressure): dizziness, fainting, light-headedness	✓		
Stroke (cerebrovascular hemorrhage): bleeding in the brain, vision changes, difficulty speaking, weakness on one side of the body, dizziness, lack			✓	

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	
of coordination or poor balance			
Transient ischaemic attack: 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			✓
Pulmonary Hemorrhage (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)			✓

* including colour tinge, increased brightness of light and blurred vision.
 + An allergic reaction can be a rash, itching, a swollen face, swollen lips or shortness of breath. If this ever happens to you, discontinue SILDENAFIL and notify your doctor or pharmacist

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

HOW TO STORE IT

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

This document, plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltée, Laval, Québec, H7L 3W9

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