

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSILDENAFIL

Sildenafil Citrate Tablets

Read this carefully before you start taking **SILDENAFIL** 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 **SILDENAFIL**.

What is SILDENAFIL used for:

SILDENAFIL 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.

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

How does SILDENAFIL work:

SILDENAFIL 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 SILDENAFIL?

Medicinal ingredients: sildenafil (as sildenafil citrate).

Non-medicinal ingredients:

croscarmellose sodium, dibasic calcium phosphate, FD & C Blue #2/indigo carmine aluminum lake, microcrystalline cellulose, magnesium stearate, polyethylene glycol, talc and titanium dioxide.

SILDENAFIL comes in the following dosage:

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

Do not use SILDENAFIL 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 SILDENAFIL 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 the nonmedicinal ingredients in SILDENAFIL.
- 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 SILDENAFIL. 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: SILDENAFIL may cause a sudden decrease or loss of vision. If this happens, stop taking SILDENAFIL and tell your healthcare professional right away.

Ear Problems: SILDENAFIL may cause sudden decrease or loss of hearing, dizziness or ringing in the ears. If you experience these symptoms, stop taking SILDENAFIL 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 SILDENAFIL. Dizziness or altered vision (colour, light sensitivity, blurry vision, eye pain, red eyes) can occur while using SILDENAFIL.

Sexual Health:

- SILDENAFIL 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: SILDENAFIL 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 SILDENAFIL 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 SILDENAFIL include:

- 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 to treat erectile dysfunction
 - Grapefruit juice may increase the levels of SILDENAFIL in your blood
 - High fat meals may delay the effect of SILDENAFIL

How to take SILDENAFIL:

- Always take SILDENAFIL as directed by your healthcare professional. Talk to your healthcare professional if you are unsure.
- Take SILDENAFIL about 30 to 60 minutes before sexual activity. You may take SILDENAFIL 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 SILDENAFIL to work.

- Take with or without food. However, SILDENAFIL may take longer to work if you take it with a high-fat meal.
- Swallow tablet whole with some water.

Recommended dose:

Tablets: Your healthcare professional can determine the dose that works best for you.

The maximum dose is 100 mg per day. 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 healthcare professional may start you at the lowest dose of SILDENAFIL.

Overdose:

If you think you, or a person you are caring for, have taken too much SILDENAFIL, 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 SILDENAFIL?

These are not all the possible side effects you may have when taking SILDENAFIL. 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	
LESS COMMON			
Ear problems: sudden decrease or loss of hearing, ringing in the ears		√	

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	
Eye problems: 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			√
RARE			
Serious skin reactions: 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			√
VERY RARE			
Priapism: erection lasting more than 4 hours			√
UNKNOWN			
Allergic reactions: rash, hives, itch swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Arrhythmia/tachycardia, palpitations: fast or irregular heart beat , heart rate increased			√
Chest pain			√
Cough		√	
Fever		√	
Hypotension (low blood pressure): dizziness, fainting, lightheadedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	√		
Myocardial infarction (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.			√
Nosebleeds		√	

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	
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			√
Seizures: uncontrollable shaking with or without loss of consciousness			√
Shortness of breath		√	
Stroke (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			√
Transient global amnesia (temporary memory loss)		√	
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.			√

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 freeze.
- Do not take SILDENAFIL after the expiry date shown on the package.
- Always keep SILDENAFIL out of reach and sight of children.

If you want more information about SILDENAFIL:

- 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.sivem.ca, or by calling 1-855-788-3153.

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