# Sildenafil

### What is sildenafil?

<u>Sildenafil</u> relaxes muscles of the blood vessels and increases blood flow to particular areas of the body.

Sildenafil under the name Viagra is used to treat erectile dysfunction (impotence) in men.

## Warnings

Do not take sildenafil if you are also using a nitrate drug for chest pain or heart problems, including <u>nitroglycerin</u>, <u>isosorbide dinitrate</u>, <u>isosorbide mononitrate</u>, and some recreational drugs such as "poppers". Taking sildenafil with a nitrate medicine can cause a sudden and serious decrease in blood pressure.

Some medicines can cause unwanted or dangerous effects when used with sildenafil. Tell your doctor about all your current medicines, especially <u>riociguat</u> (<u>Adempas</u>). Do not take sildenafil with riociguat.

Contact your doctor or seek emergency medical attention if your erection is painful or lasts longer than 4 hours. A prolonged erection (<u>priapism</u>) can damage the penis.

Stop using sildenafil and get emergency medical help if you have sudden vision loss.

# Before taking this medicine

You should not use sildenafil if you are allergic to it, or:

• if you take other medicines to treat pulmonary arterial hypertension, such as riociguat (Adempas).

Do not take this medicine if you are also using a nitrate drug for chest pain or heart problems. This includes nitroglycerin, isosorbide dinitrate, and isosorbide mononitrate. Nitrates are also found in some recreational drugs such as amyl nitrate or nitrite ("poppers"). **Taking sildenafil with a nitrate medicine can cause a sudden and serious decrease in blood pressure.** 

To make sure sildenafil is safe for you, tell your doctor if you have ever had:

- heart problems (chest pain, a heart rhythm disorder, <u>heart attack</u>);
- high or low blood pressure;
- blood circulation problems;

- retinitis pigmentosa (an inherited condition of the eye);
- blindness in one or both eyes;
- bleeding problems;
- a stomach ulcer;
- pulmonary veno-occlusive disease (PVOD);
- liver or kidney disease;
- a blood cell disorder such as sickle cell anemia, multiple myeloma, or leukemia;
- a physical deformity of the penis (such as Peyronie's disease); or
- if you have been told you should not have sexual intercourse for health reasons.

Sildenafil can decrease blood flow to the optic nerve of the eye, causing sudden vision loss. This has occurred in a small number of people taking sildenafil, most of whom also had heart disease, diabetes, <u>high blood pressure</u>, <u>high cholesterol</u>, or certain pre-existing eye problems, and in those who smoked or were over 50 years old. It is not clear whether this medicine is the actual cause of vision loss.

This medicine is not expected to harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant. Women with pulmonary arterial hypertension should not stop taking sildenafil without talking to their doctor.

It is not known whether sildenafil passes into breast milk or if it could harm a nursing baby. Tell your doctor if you are breast-feeding a baby. Women with pulmonary arterial hypertension should not stop taking sildenafil without talking to their doctor.

Do not give this medication to anyone under 18 years old without medical advice.

### How should I take sildenafil?

Take sildenafil exactly as it was prescribed for you. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Viagra is usually taken only when needed, 30 minutes to 1 hour before sexual activity. You may take it up to 4 hours before sexual activity. Do not take Viagra more than once per day.

Shake the **oral suspension** (liquid) before you measure a dose. Use the dosing syringe provided, or use a medicine dose-measuring device (not a kitchen spoon).

Viagra can help you have an erection when sexual stimulation occurs. An erection will not occur just by taking a pill. Follow your doctor's instructions.

During sexual activity, if you become dizzy or nauseated, or have pain, <u>numbness</u>, or tingling in your chest, arms, neck, or jaw, stop and call your doctor right away. You could be having a serious side effect of sildenafil.

Store at room temperature away from moisture and heat.

## What happens if I miss a dose?

Since Viagra is used as needed, you are not likely to miss a dose.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

### What to avoid

Drinking alcohol with sildenafil can cause side effects.

<u>Grapefruit</u> may interact with sildenafil and lead to unwanted side effects. Avoid the use of grapefruit products.

Avoid using any other medicines to treat impotence, such as <u>alprostadil</u> or <u>yohimbine</u>, without first talking to your doctor.

### Sildenafil side effects

Get emergency medical help if you have **signs of an allergic reaction to sildenafil:** <u>hives</u>; difficulty breathing; swelling of your face, lips, tongue, or throat.

## Stop taking sildenafil and get emergency medical help if you have:

- heart attack symptoms chest pain or pressure, pain spreading to your jaw or shoulder, nausea, sweating;
- vision changes or sudden vision loss;
- erection is painful or lasts longer than 4 hours (prolonged erection can damage the penis);
- ringing in your ears, or sudden hearing loss;
- irregular heartbeat;
- swelling in your hands, ankles, or feet;
- shortness of breath:
- seizure (convulsions); or
- a light-headed feeling, like you might pass out.

Common sildenafil side effects may include:

- flushing (warmth, redness, or tingly feeling);
- headache, dizziness;
- heartburn, nausea, or upset stomach
- abnormal vision (blurred vision, changes in color vision)
- runny or stuffy nose, nosebleeds;
- sleep problems (insomnia); or
- muscle pain, back pain.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

# What other drugs will affect sildenafil?

Do not take sildenafil with similar medications such as avanafil (Stendra), tadalafil (Cialis) or vardenafil (Levitra). Tell your doctor about all other medications you use for erectile dysfunction.

Do not take sildenafil if you take other medicines to treat pulmonary arterial hypertension, such as riociguat (Adempas).

Do not take sildenafil if you are also using a nitrate drug for chest pain or heart problems. This includes nitroglycerin, isosorbide dinitrate, and isosorbide mononitrate. Nitrates are also found in some recreational drugs such as amyl nitrate or nitrite ("poppers"). Taking sildenafil with a nitrate medicine can cause a sudden and serious decrease in blood pressure.

In addition, tell your doctor about all your other medicines, especially:

- drugs to treat high blood pressure or a prostate disorder;
- antifungal medicine ketoconazole or itraconazole; or
- medicine to treat HIV/AIDS ritonavir and others.

This list is not complete. Other drugs may interact with sildenafil, including prescription and over-the-counter medicines, <u>vitamins</u>, and <u>herbal products</u>. Not all possible drug interactions are listed here.