

Package leaflet: Information for the patient

Sildenafil Actavis 25 mg, 50 mg, and 100 mg film-coated tablets
Sildenafil Actavis 25 mg film-coated tablets
Sildenafil Actavis 50 mg film-coated tablets
Sildenafil Actavis 100 mg film-coated tablets
sildenafil

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please ask your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

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1. What is Sildenafil Actavis and what is it used for?

Sildenafil Actavis contains the active substance sildenafil, which belongs to a group of medicines called "phosphodiesterase type 5 (PDE5) inhibitors". It works by relaxing the blood vessels in the penis, allowing blood to flow into the penis during sexual arousal. You will only get an erection with Sildenafil Actavis if you are sexually stimulated.

Sildenafil Actavis is used to treat adult men with erectile dysfunction, sometimes referred to as impotence. This is when a man cannot achieve or maintain an erection sufficient for sexual activity.

2. When should you not use Sildenafil Actavis or be extra careful with it?

When should you not use this medicine

- If you are allergic to any of the ingredients in this medicine. These ingredients can be found in section 6.
- If you are taking medicines called "nitrates," as this combination can lead to a dangerous drop in your blood pressure. Tell your doctor that you are taking these medicines, which are often given for relief of angina pectoris (or "chest pain"). If you are not sure, ask your doctor or pharmacist.

- If you are taking medicines that release nitric oxide, such as amyl nitrite (“poppers”), as this combination can also lead to a dangerous drop in your blood pressure.
- You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (this is high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (this is high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as Sildenafil Actavis, have been shown to increase the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure, contact your doctor.
- If you have a severe heart problem or liver problem.
- If you have recently had a stroke or a heart attack or if you have low blood pressure.
- If you have a certain rare inherited eye disease (such as retinitis pigmentosa).
- If you have ever had a loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION).

When should you be extra careful with this medicine

Contact your doctor, pharmacist, or nurse before using this medicine.

- If you have sickle cell anemia (an abnormality of red blood cells), leukemia (blood cell cancer), multiple myeloma (bone marrow cancer).
- If you have a deformity of your penis or Peyronie's disease.
- If you have heart problems. In this case, your doctor should carefully check whether your heart can handle the extra strain of sexual activity.
- If you have a stomach ulcer, or a bleeding disorder (such as hemophilia).
- If you suddenly experience a decrease or loss of vision, stop taking Sildenafil Actavis and contact your doctor immediately.

You should not use Sildenafil Actavis in combination with other oral or local treatments for erectile dysfunction.

You should not use Sildenafil Actavis with pulmonary arterial hypertension (PAH) treatments that contain sildenafil or other PDE5 inhibitors.

You should not use Sildenafil Actavis if you do not have erectile dysfunction.

You should not use Sildenafil Actavis if you are a woman.

Special precautions for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide to prescribe you a lower dose.

Children and adolescents

Sildenafil Actavis should not be used by individuals under 18 years of age.

Are you taking any other medicines

Are you taking any other medicines besides Sildenafil Actavis, have you recently taken any, or is there a possibility that you will take other medicines soon? Then tell your doctor or pharmacist.

Sildenafil Actavis tablets can affect the action of certain medicines, especially medicines used for "chest pain." In a medical emergency, you should tell your doctor, pharmacist, or nurse that you have used Sildenafil Actavis and when you did so. Do not use Sildenafil Actavis in combination with other medicines unless your doctor has indicated that you can.

You should not use Sildenafil Actavis if you are taking medicines called "nitrates," as the combination of these medicines can lead to a dangerous drop in your blood pressure. Always tell your doctor, pharmacist, or nurse that you are using this type of medicine, which is often used to relieve angina pectoris (or "chest pain").

You should not use Sildenafil Actavis if you are taking medicines that release nitric oxide, such as amyl nitrite ("poppers"), as this combination can also lead to a dangerous drop in your blood pressure.

Are you already taking riociguat? Then tell your doctor or pharmacist.

When you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose of Sildenafil Actavis (25 mg).

Some patients receiving alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which can be caused by low blood pressure when sitting or standing up quickly. Certain patients have experienced these symptoms when using Sildenafil Actavis concurrently with alpha-blockers. The likelihood of this is greatest within 4 hours after taking Sildenafil Actavis. To reduce the chance of these symptoms occurring, your daily dose of alpha-blocker should be stable before you start using Sildenafil Actavis. Your doctor may prescribe you a lower starting dose (25 mg) of Sildenafil Actavis.

Are you already taking medicines containing sacubitril/valsartan, used to treat heart failure? Then tell your doctor or pharmacist.

What to watch out for with food, drink, and alcohol

Sildenafil Actavis can be taken with or without food. However, you may find that it takes a little longer for Sildenafil Actavis to work if you take it with a heavy meal.

Drinking alcohol can temporarily reduce your ability to get an erection. To get the maximum effect from your medicine, you are advised not to drink large amounts of alcohol before taking Sildenafil Actavis.

Pregnancy, breastfeeding, and fertility

Sildenafil Actavis is not indicated for use by women.

Driving and using machines

Sildenafil Actavis can cause dizziness and can affect your vision. You should be aware of how you react to Sildenafil Actavis before driving or using a machine.

Sildenafil Actavis contains lactose and sodium

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, which means it is essentially 'sodium-free'.

3. How to use Sildenafil Actavis?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist. The recommended starting dose is 50 mg.

You should not take Sildenafil Actavis more than once a day.

Take Sildenafil Actavis about one hour before you plan to have sex. Swallow the tablet whole with a glass of water.

If you feel that the effect of Sildenafil Actavis is too strong or too weak, inform your doctor or pharmacist.

Sildenafil Actavis only helps you to get an erection when you are sexually aroused. The time it takes for Sildenafil Actavis to work varies from person to person, but it usually takes half an hour to an hour. It may take longer for Sildenafil Actavis to work if you have eaten a heavy meal.

If Sildenafil Actavis does not help you get an erection or if the erection does not last long enough to complete sexual intercourse, you should tell your doctor.

If you have taken too much of this medicine

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the effectiveness.

You should not take more tablets than your doctor has told you.

Contact your doctor if you have taken more tablets than prescribed.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects reported in association with the use of sildenafil are usually mild to moderate and of short duration.

If you experience any of the following serious side effects, stop taking Sildenafil Actavis and seek medical help immediately:

- Allergic reaction - this occurs sometimes (may affect up to 1 in 100 people)
Symptoms include sudden wheezing, difficulty breathing or dizziness, swelling of the eyelids, face, lips, or throat.
- Chest pain - this occurs sometimes
If this occurs during or after intercourse:
 - Get into a semi-sitting position and try to relax
 - Do not use nitrates to treat your chest pain
- Prolonged and sometimes painful erections - this occurs rarely (may affect up to 1 in 1000 people)
If you have an erection that lasts more than 4 hours, contact your doctor immediately.
- Sudden decrease or loss of vision - this occurs rarely
- Serious skin reactions - this occurs rarely
Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals, and around the eyes, fever.
- Seizures or fits - this occurs rarely

Other side effects:

Very common (may affect more than 1 in 10 people): headache.

Common (may affect up to 1 in 10 people): nausea, flushing, hot flushes (symptoms include a sudden feeling of heat in your upper body), indigestion, visual color distortions, blurred vision, visual disturbances, blocked nose, and dizziness.

Sometimes (may affect up to 1 in 100 people): vomiting, skin rash, eye irritation, bloodshot eyes/red eyes, eye pain, seeing flashes of light, visual brightness, sensitivity to light, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, spinning sensation, ringing in the ears, dry mouth, blocked or congested sinuses, inflammation of the nasal lining (symptoms include runny nose, sneezing, and blocked nose), upper abdominal pain, gastroesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in arms or legs, nosebleed, feeling hot and feeling tired.

Rarely (may affect up to 1 in 1000 people): fainting, stroke, heart attack, irregular heartbeat, temporary decrease in blood supply to parts of the brain, feeling of tightness in the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal feeling in the eye, swelling of the eye or eyelid, small particles or spots in front of the eyes, seeing halos around lights, dilation of the pupil of the eye, discoloration of the eye, bleeding penis, presence of blood in semen, dry nose, swelling of the inside of the nose, irritability, and sudden decrease or loss of hearing.

Post-marketing cases of unstable angina (a heart condition) and sudden death have been rarely reported. Note, most, but not all, men who experienced these side effects had pre-existing heart problems before taking this medicine. It is impossible to determine whether there was a direct link between these events and the use of sildenafil.

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store Sildenafil Actavis?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 30°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

Contents of the pack and other information

What substances are in this medicine

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg, or 100 mg sildenafil (as citrate).
- The active substance is sildenafil. Each tablet contains 25 mg sildenafil (as citrate).
- The active substance is sildenafil. Each tablet contains 50 mg sildenafil (as citrate).
- The active substance is sildenafil. Each tablet contains 100 mg sildenafil (as citrate).
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone K29-32, sodium croscarmellose, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol 6000, indigo carmine aluminum lake (E132).

What Sildenafil Actavis looks like and contents of the pack

Film-coated tablet

Sildenafil Actavis 25 mg film-coated tablets are blue, oval, biconvex tablets, 10.0 x 5.0 mm, and marked on one side with "SL25".

Sildenafil Actavis 50 mg film-coated tablets are blue, oval, biconvex tablets, 13.0 x 6.5 mm and marked on one side with "SL50".

Sildenafil Actavis 100 mg film-coated tablets are blue, oval, biconvex tablets, 17.0 x 8.5 mm and marked on one side with "SL100".

The tablets are available in blister packs of 1, 2, 4, 8, 12, or 24 tablets.

Some packages may not be available in your country.

Marketing authorization holder and manufacturer

Marketing authorization holder

Actavis Group PTC ehf.

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Manufacturer Actavis Ltd.

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Other sources of information

Detailed information about this medicine is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.