

Sildenafil Actavis 100 mg film-coated tablets

Sildenafil

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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2. Before you take Sildenafil Actavis
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1. WHAT SILDENAFIL ACTAVIS IS AND WHAT IT IS USED FOR

Sildenafil Actavis belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Sildenafil Actavis will only help you to get an erection if you are sexually stimulated. You should not take Sildenafil Actavis if you do not have erectile dysfunction. You should not take Sildenafil Actavis if you are a woman.

Sildenafil Actavis is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

2. BEFORE YOU TAKE SILDENAFIL ACTAVIS

Do not take Sildenafil Actavis

- If you are taking medicines containing nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of Sildenafil Actavis.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as *retinitis pigmentosa*).
- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Take special care with Sildenafil Actavis

Tell your doctor

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie's Disease.
- If you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Sildenafil Actavis and contact your doctor immediately.

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

Special considerations for children and adolescents

Sildenafil Actavis should not be given to individuals under the age of 18.

Special considerations for patients with kidney or liver problems

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription.

Sildenafil Actavis tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any health care professional treating your condition that you have taken Sildenafil Actavis and when you did. Do not take Sildenafil Actavis with other medicines unless your doctor tells you that you can.

You should not take Sildenafil Actavis if you are taking medicines called nitrates, as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take Sildenafil Actavis if you are using any of the drugs known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a potentially dangerous decrease in your blood pressure.

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

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate problems may experience dizziness or light-headedness, which may be caused by low pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking sildenafil with alpha-blockers. This is most likely to occur within 4 hours after taking Sildenafil Actavis. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Sildenafil Actavis. Your doctor may start you on a lower dose (25 mg) of Sildenafil Actavis.

Taking Sildenafil Actavis with food and drink

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

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

Driving and using machines

Sildenafil Actavis can cause dizziness and can affect vision. You should be aware of how you react to Sildenafil Actavis before you drive or use machinery.

Important information about some of the ingredients of Sildenafil Actavis

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking Sildenafil Actavis.

3. HOW TO TAKE SILDENAFIL ACTAVIS

Always take Sildenafil Actavis exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 50 mg.

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

You should take Sildenafil Actavis about one hour before sexual activity. Swallow the tablet whole with a glass of water.

If you have the impression that the effect of Sildenafil Actavis is too strong or too weak, talk to your doctor or pharmacist.

Sildenafil Actavis will only help you to get an erection if you are sexually stimulated. The amount of time Sildenafil Actavis takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Sildenafil Actavis takes longer to work if you take it with a heavy meal.

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

If you take more Sildenafil Actavis than you should

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

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sildenafil Actavis can cause side effects, although not everybody gets them. These effects are normally mild to moderate and of short duration.

If you have chest pains during or after intercourse:

- Get in a semi-sitting position and try to relax.
- **Do not use nitrates** to treat your chest pain.
- Contact your doctor immediately.

All medicines including Sildenafil Actavis can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking this medicinal product: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking sildenafil. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking the medicinal product and contact your doctor immediately.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data).

A very common side effect is headache.

Common side effects include: facial flushing, indigestion, effects on vision (including colour tinge to vision, light sensitivity, blurred vision or reduced sharpness of vision) stuffy nose and dizziness.

Uncommon side effects include: vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes /red eyes, eye pain, double vision, abnormal sensation in the eye, watery eyes, irregular or rapid heartbeat, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, nausea, dry mouth, penile bleeding, presence of blood in semen and/or urine, chest pain and feeling tired.

Rare side effects include: high blood pressure, low blood pressure, fainting, stroke, heart attack, nosebleed and sudden decrease or loss of hearing.

Additional side effects reported from post-marketing experience include: pounding heartbeat, chest pain, sudden death or temporary decreased blood flow to parts of the brain. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to sildenafil. Cases of convulsions or seizures and serious skin reactions characterised by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor.

5. HOW TO STORE SILDENAFIL ACTAVIS

Keep out of the reach and sight of children

Do not use Sildenafil Actavis after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sildenafil Actavis contains

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

What Sildenafil Actavis looks like and contents of the pack

Film-coated tablet

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

The tablets are provided in blister packs containing 1, 2, 4, 8 or 12 tablets.

Some pack sizes may not be marketed in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.
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This leaflet was last approved in March 2013.

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