

## SILDENAFIL ACTAVIS

film coated tablet

contains sildenafil (as citrate)

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Sildenafil Actavis tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sildenafil Actavis against the benefits they expect it will have for you.

**It should be used only under strict medical supervision.**

**If you have any concerns about using this medicine, ask your pharmacist or doctor.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### WHAT SILDENAFIL ACTAVIS IS USED FOR

Sildenafil Actavis is used to treat erectile dysfunction, more commonly known as impotence, in men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

Sildenafil Actavis belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.

Sildenafil Actavis will work only if you are sexually excited.

Sildenafil Actavis will not increase your sex drive.

Sildenafil Actavis is not for use in women. This medicine is available only with a doctor's prescription.

#### BEFORE YOU TAKE SILDENAFIL ACTAVIS

**YOU MUST NOT TAKE SILDENAFIL ACTAVIS IF YOU ARE TAKING ANY NITRATE MEDICATION. IT MAY LEAD TO A SEVERE DROP IN YOUR BLOOD PRESSURE, WHICH MAY BE DIFFICULT TO TREAT.**

**BECAUSE SEXUAL ACTIVITY MAY PLACE A STRAIN ON YOUR HEART, YOUR DOCTOR WILL NEED TO CHECK WHETHER YOU ARE FIT ENOUGH TO TAKE SILDENAFIL ACTAVIS.**

*When you must not take it*

Do not take Sildenafil Actavis if:

1. you are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates.  
Nitrate medicines include glyceryl trinitrate (also called nitroglycerin). Common trade names include tablets; such as Anginine, Lycinate and Nitrostat; patches such as Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran; sprays such as Nitrolingual and Glytrin and injections such as Glyceryl trinitrate concentrate.  
Common trade names for other nitrate preparations include tablets such as Imdur Durules, Monodur durules, Sorbidin, Isordil, Corangin, ISMO 20, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside. There may be other trade names not listed here.
2. you are using amyl nitrite
3. you have heart or blood vessel problems that make sexual intercourse inadvisable
4. you have suffered a heart attack or stroke in the last 6 months
5. you have severe liver problems
6. your blood pressure is unusually high or low or is not effectively treated
7. you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
8. you have an eye disease called retinitis pigmentosa
9. you have an allergy to:
  - Sildenafil Actavis or similar medicines
  - any of the ingredients listed at the end of this leaflet.An allergic reaction can include:
  - hives, itching or skin rash
  - swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing
10. the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright
11. the expiry date on the pack has passed. If it has expired or is damaged, return it to your pharmacist for disposal.

#### *Before you start to take it*

Tell your doctor if:

- You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- You have any other heart or blood vessel problems.
- You have previously had sudden loss of eyesight in one or both eyes.

- You have any of the following medical conditions:
  - diabetes, especially if you also have eye problems
  - kidney or liver problems
  - leukaemia (cancer of the blood cells)
  - multiple myeloma (a cancer of the bone marrow)
  - any disease or deformity of your penis
  - any bleeding disorder such as haemophilia
  - stomach ulcer
  - a disease of the blood called sickle cell anaemia
  - colour vision problems
  - previously experienced sudden decrease or loss of hearing.
- You are receiving any other treatment for impotence.
- You are taking medicines to treat high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension) including Revatio or traicleer (bosentan).
- You have any other medical conditions.

**If you have not told your doctor about any of the above, tell him/her before you start taking Sildenafil Actavis.**

#### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Do not take Sildenafil Actavis if you are using nitrate medicines for angina.

Some medicines and Sildenafil Actavis may interfere with each other. These include:

- cimetidine, a medicine used to treat ulcers
- some medicines used to treat fungal infections including ketoconazole and itraconazole
- some antibiotics including erythromycin and rifampicin
- some protease inhibitors such as ritonavir and saquinavir for the treatment of HIV infection
- medicines called alpha-blockers. These are used to treat high blood pressure or prostate problems
- medicines used to treat high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension) including Traicleer (bosentan).

These medicines may be affected by Sildenafil Actavis, or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

If you require further advice, you should talk with your doctor or pharmacist.

#### HOW TO TAKE SILDENAFIL ACTAVIS

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

#### How much to take

Your doctor will decide the correct dose for you depending on your condition and response.

This can be one 25 mg tablet a day or one 50 mg tablet a day or one 100 mg tablet a day.

**Do not take more than one dose of Sildenafil Actavis a day.**

**It is important to take Sildenafil Actavis exactly as your doctor or pharmacist has told you.**

#### When to take it

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

The amount of time Sildenafil Actavis takes to start working varies from person to person, but it normally takes between half an hour and one hour.

You may find Sildenafil Actavis takes longer to work if you take it with a heavy meal.

Sildenafil Actavis will work only if you are sexually excited.

#### If you take too much (overdose)

**Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Sildenafil Actavis.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much Sildenafil Actavis you are more likely to experience side effects.

## WHILE YOU ARE TAKING SILDENAFIL ACTAVIS

### Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

Stop using Sildenafil Actavis if you have a loss of eyesight in one or both eyes, experienced loss of hearing or have an erection that persists more than 4 hours. Seek medical attention urgently.

If Sildenafil Actavis does not help you get an erection or if your erection does not last long enough to complete sexual intercourse, tell your doctor. In these cases, your doctor may decide that you need a higher dose.

If you are about to start taking any new medicines, especially nitrates, tell your doctor and pharmacist that you are taking Sildenafil Actavis. See "Before you take Sildenafil Actavis" for a list of common nitrate medications.

### Things you must not do

Do not use the drug amyl nitrite (sometimes called "poppers") while you are taking Sildenafil Actavis.

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctor knows you are taking Sildenafil Actavis.

Do not give your medicine to anyone else, even if they have the same condition as you.

### Things to be careful of

**Be careful drinking alcohol while taking Sildenafil Actavis. Drinking alcohol can temporarily impair the ability to get an erection. Do not drink large amounts of alcohol before sexual activity.**

**If you experience changes in vision, or dizziness, when taking Sildenafil Actavis, you should not drive or operate machinery.**

## SIDE EFFECTS

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sildenafil Actavis.**

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by this list of possible side effects. You may not get any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:**

- headache, dizziness
- flushing
- indigestion
- heartburn
- nasal congestion
- sinus congestion
- swelling of your nose
- diarrhoea
- rash
- dry mouth or dry throat
- dry nose
- dry eye
- tightness in your throat
- feeling hot or irritable
- redness in your mouth or tongue.

**Tell your doctor as soon as possible if you notice any of the following:**

- unusual heart beat
- urinary tract infection (stinging or burning urine, more frequent need to pass urine)
- blood in the urine
- persistent headache or fainting
- bleeding from the nose
- pain or tingling in your hands, toes or feet
- decreased sensitivity or numbness in your mouth
- irritation or feeling of having something in the eye
- swollen or puffy eye(s)
- fatigue, pain in or around the eyes
- "red eye" due to swollen blood vessels in the white part of the eye and in the eyelids.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- signs of allergy such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts
- chest pain
- increased heart rate
- sudden decrease or loss of hearing

- seizures, fits or convulsions
- your erection be increased, painful or may persist for longer than usual. If your erection continues for four hours, or sooner if there is pain, you should seek medical attention urgently.
- rarely men have lost eyesight sometime after taking drugs to treat erectile dysfunction (known as impotence). If you lose eyesight in one or more eyes, or experience changes in vision such as blurring, a blue colour to your vision or a greater awareness of light, seek medical attention urgently.
- changes to your normal vision such as:
  - red or yellow colour tinges to your vision or colourless objects appear coloured
  - you see a halo around lights, sparks or lights when your eyes are closed.

This is not a complete list of all possible side effects. Others may occur in some people and there may be side effects not yet known.

**If you notice any other symptoms that worry you, check with your doctor.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

## AFTER TAKING SILDENAFIL ACTAVIS

### Storage

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## PRODUCT DESCRIPTION

### What it looks like

- Sildenafil Actavis (sildenafil citrate) 25 mg are white to off-white coloured, diamond shaped, biconvex, film coated tablets with "U" debossed on one side and "25" debossed on other side.
- Sildenafil Actavis (sildenafil citrate) 50 mg are white to off-white coloured, diamond shaped, biconvex, film coated tablets with "U" debossed on one side and "50" debossed on other side.
- Sildenafil Actavis (sildenafil citrate) 100 mg are white to off-white coloured, diamond shaped, biconvex, film coated tablets with "U" debossed on one side and "100" debossed on other side.

Available\* in blister cartons of 4, 8 and 12 tablets.

\*not all pack sizes are currently marketed.

### Ingredients

**Each Sildenafil Actavis tablet contains:**

Active ingredient:

- sildenafil citrate

Inactive ingredients:

- lactose
- maize starch
- sodium starch glycollate Type A
- povidone
- colloidal anhydrous silica
- hypromellose
- macrogol 400
- magnesium stearate
- Opadry complete film coating system  
06B580001 white
- Opadry AMB complete film coating system  
OY-S29019 clear

*Supplier*

Sildenafil Actavis is supplied in Australia by:

**Actavis Pty Ltd**

Level 5, 117 Harrington Street  
The Rocks, Sydney NSW 2000  
Australia

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**Australian Register Numbers**

25 mg tablet: AUST R 202925  
50 mg tablet: AUST R 202924  
100 mg tablet: AUST R 202923