

APO-Sildenafil

Contains the active ingredient sildenafil (as sildenafil citrate)

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Sildenafil. It contains the active ingredient sildenafil.

It 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Sildenafil 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 will work only if you are sexually excited.

Sildenafil will not increase your sex drive.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

YOU MUST NOT TAKE SILDENAFIL 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.

When you must not take it

Do not take this medicine if:

- **You are being treated for angina (chest pain) or other heart conditions with certain medicines called nitrates. It includes glyceryl trinitrate (injection, tablets, sprays or patches), isosorbide salts, sodium nitroprusside, amyl nitrite, nicorandil or organic nitrates in any form.**

- **You have or have had any of the following:**
 - heart or blood vessel problems that make sexual intercourse inadvisable
 - suffered a heart attack or stroke in the last 6 months
 - severe liver problems
 - blood pressure is unusually high or low or is not effectively treated
 - loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)
 - eye disease called retinitis pigmentosa.
- **You are hypersensitive to, or have had an allergic reaction to, sildenafil or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:
 - 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.
3. You are taking or using any of the following medications:
 - other medicines containing sildenafil or any other treatment for male erectile dysfunction (impotence). Other medicines used to treat impotence include tadalafil and vardenafil
 - any treatments for pulmonary arterial hypertension (PAH). PAH is a type of high blood pressure that affects the arteries of the lungs and right side of your heart.
4. You are planning to have surgery or an anaesthetic.
5. You are currently receiving or are planning to receive dental treatment.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with sildenafil. 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Do not take sildenafil if you are using nitrate medicines.

Other medicines not listed above may also interact with sildenafil.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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 a day.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take your dose of sildenafil about one hour before you intend to have sex.

Sildenafil Tablets 25 mg, 50 mg or 100 mg

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

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

Sildenafil will work only if you are sexually excited.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Stop using sildenafil 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 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.

See "Before you take Sildenafil" for a list of common nitrate medications.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are about to have any blood tests

- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

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

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.

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

Things to be careful of

Be careful drinking alcohol while taking sildenafil.

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, you should not drive or operate machinery.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking sildenafil or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache, dizziness
- flushing
- indigestion or heartburn
- nasal and/or sinus congestion
- swelling of your nose
- diarrhoea
- rash
- tightness in your throat
- feeling hot or irritable
- dry or irritated eye(s)

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

These may be serious side effects and you may need medical attention:

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

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- chest pain
- increased heart rate
- sudden decrease or loss of hearing
- seizures, fits or convulsions

- visual disturbances 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.

Very rarely your erection 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 some time after taking drugs to treat erectile dysfunction (known as impotence). It is not known at this time if sildenafil causes this. If you lose eyesight in one or more eyes, seek medical attention urgently.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to sildenafil, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Sildenafil looks like

- **25 mg tablets**
The 25 mg tablets are white diamond shaped, biconvex film-coated tablets, engraved "APO" on one side and "SIL25" on the other side.
- **50 mg tablets**
The 50 mg tablets are white diamond shaped, biconvex film-coated tablets, engraved "APO" on one side and "SIL50" on the other side.
- **100 mg tablets**
The 100 mg tablets are white diamond shaped, biconvex film-coated tablets, engraved "APO" on one side and "SIL100" on the other side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

APO-Sildenafil 25 mg tablets:

Each tablet contains 25 mg of sildenafil as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Magnesium stearate
- Croscarmellose sodium
- Hydroxypropylcellulose
- Hypromellose
- Macrogol 8000
- Titanium dioxide

APO-Sildenafil 50 mg tablets:

Each tablet contains 50 mg of sildenafil as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Magnesium stearate
- Croscarmellose sodium
- Hydroxypropylcellulose
- Hypromellose
- Macrogol 8000
- Titanium dioxide

APO-Sildenafil 100 mg tablets:

Each tablet contains 100 mg of sildenafil as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Magnesium stearate
- Croscarmellose sodium
- Hydroxypropylcellulose
- Hypromellose
- Macrogol 8000
- Titanium dioxide

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Sildenafil 25 mg tablets blister pack of 1, 4, 8, 12 tablets: AUST R 164811
- APO-Sildenafil 50 mg tablets blister pack of 1, 4, 8, 12 tablets: AUST R 164813

- APO-Sildenafil 100 mg tablets
blister pack of 1, 4, 8,12 tablets:
AUST R 164806

Sponsor

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