APX-SILDENAFIL
(sildenafil citrate)

Consumer Medicine Information

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

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine 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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What this medicine is used for

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

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Sildenafil 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 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 only work if you are sexually excited.

It will not increase your sex drive.

Sildenafil is not for use in women.

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

Before you take this medicine

You must not take sildenafil if you are taking nitrates or nitrite medications.

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 this medicine.

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.**
  Nitrate medicines include glyceryl trinitrate (also called nitroglycerin). Common tradenames 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 Gliceryl trinitrate concentrate.
  Common tradenames 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 tradenames not listed here.
- **you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).**
  GCS is a type of medicine used to treat high blood pressure in the blood vessels in the lungs caused by blood clots in the lungs (chronic thromboembolic pulmonary hypertension, CTEPH) or narrowing of the vessels that carry blood from the heart to the lungs (pulmonary arterial hypertension or PAH).
- **you have heart or blood vessel problems that make sexual intercourse inadvisable**
- **you have suffered a heart attack or stroke in the last 6 months**
- **you have severe liver problems**
- **your blood pressure is unusually high or low or is not effectively treated**
- **you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)**
- **you have an eye disease called retinitis pigmentosa**
- **you have an allergy to:**
  Sildenafil citrate or similar medicines or 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, tongue which may lead to difficulty swallowing or breathing.
- **the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright.**
- **the expiry date (EXP) printed 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 allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- **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 taking 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 Tracleer (bosentan).**

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.
Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 if you are using nitrate medicines for angina.

Do not take Sildenafil if you are taking guanylate cyclase stimulators (GCS), such as Adepmas (riociguat).

Some medicines and this one 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.
- Tracleer (bosentan), a medicine used to treat high blood pressure in the vessels of the lungs.

You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Sildenafil.

Ask your doctor or pharmacist, if you are not sure if you are taking any of these medicines.

How to take this medicine

Take Sildenafil exactly as your doctor has prescribed.

Follow all directions given to you by your doctor and pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, 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 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.

Swallow the tablet whole with a full glass of water.

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.

If you take too much (overdose)

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

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice if you think that you or anyone else may have taken too much Sildenafil.

Do this even if there are no signs of discomfort.

While you are using this medicine

Things you must do

Stop taking 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, or Adepmas (riociguat), tell your doctor and pharmacist that you are taking Sildenafil.

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Sildenafil.

Things you must not do

Do not use drugs containing 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 this medicine, 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.

While Sildenafil helps most people, it can cause some unwanted side effects in a few people.

All medicines have side effects. If unwanted effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by this list of possible side effects.

You may not experience any of them. Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Headache
- dizziness
- flushing
- hot flushes
- indigestion
- heartburn
- nasal congestion
- sinus congestion
- swelling of your nose
- diarrhoea
- rash
- dry mouth or 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
- changes in vision such as blurring, a blue colour to your vision or a greater awareness of light
- 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 difficult 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 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 some side effects not yet known.

if you notice anything other symptoms that worry you, check with your doctor.

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

Storage and Disposal

Storage

Keep the tablets in in their pack until it is time to take them. If you take your tablets out of the pack they will not keep as well.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not store this 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 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.

Disposal

If your doctor or pharmacist tells you to stop taking Sildenafil or they have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

APX-Sildenafil 25 mg is a blue coloured, round film-coated tablet, debossed with ‘SC’ on one side and ‘25’ on other side. AUST R 186300

APX-Sildenafil 50 mg is a blue coloured, round film-coated tablet, debossed with ‘SC’ on one side and ‘50’ on other side. AUST R 186292

APX-Sildenafil 100 mg is a blue coloured, round film-coated tablet, debossed with ‘SC’ on one side and ‘100’ on other side. AUST R 186284

APX-Sildenafil is available in blister packs of 4 tablets. The 100 mg tablets are also available in a blister pack of 12 tablets.

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

Ingredients

Each APX-Sildenafil tablet contains 25 mg, 50 mg or 100 mg of sildenafil (as citrate) as the active ingredient. This medicine also contains the following:

- microcrystalline cellulose
- calcium hydrogen phosphate
- croscarmellose sodium
- hyprolose
- magnesium stearate
- hypromellose
- lactose monohydrate
- glycerol triacetate
- titanium dioxide
- indigo carmine aluminium lake

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

Distributor

This medicine is distributed in Australia by:

Arrotex Pharmaceuticals Pty Ltd
Cremorne VIC 3121

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