

APO-SILDENAFIL PHT

(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 APO-Sildenafil PHT. It contains the active ingredient sildenafil citrate.

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

Sildenafil is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs).

Sildenafil brings down pulmonary arterial blood pressure by relaxing the blood vessels in the lungs.

Do not give sildenafil to children. Sildenafil is not indicated for use in children less than 18 years of age.

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.

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 Minitrans; 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 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 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 previously had sudden loss of eyesight in one or both eyes**
- you have any of the following medical conditions:**
 - heart or blood vessel problems
 - high blood pressure
 - low blood pressure
 - 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 bleeding disorder such as haemophilia or problems with nose bleeds
 - 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 treatment for male erectile dysfunction (impotence) including Sildenafil 25 mg, 50 mg or 100 mg tablets which contains the same medicine as Sildenafil PHT 20 mg tablets. Other medicines used to treat impotence include tadalafil and vardenafil
- you are taking medicines to treat high blood pressure in the blood vessels in the lungs (pulmonary arterial hypertension) including Revatio or Tracleer (bosentan).**
- You are pregnant or planning to become pregnant.**
Sildenafil should not be used during pregnancy. Your doctor will discuss the risks with you.
- You are breastfeeding**

You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.

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).

Tell your doctor if you are taking any other medicines for pulmonary arterial hypertension.

These medicines include Tracleer (bosentan), Flolan (epoprostenol) or Ventavis (Iloprost).

Some medicines and this one may interfere with each other. These include:

- Medicines called alpha-blockers. These are used to treat high blood pressure or prostate problems
- some medicines used to treat epilepsy such as phenytoin, carbamazepine and phenobarbital
- St John's Wort, a herbal preparation that may be used to treat mild anxiety
- rifampicin used to treat leprosy or tuberculosis
- cimetidine, a medicine used to treat ulcers
- an antibiotic called erythromycin
- 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.

Avoid drinking grapefruit juice. It may increase the level of sildenafil in your blood.

You may feel lightheaded if you drink alcohol while you are taking sildenafil.

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.

The usual dose is one 20 mg tablet taken three times a day (taken 6 - 8 hours apart).

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it

Take this medicine every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

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 using sildenafil if you have a loss of eyesight in one or both eyes, or have an erection that lasts more than 4 hours. Seek medical attention urgently.

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.

Take your medicine to treat any other condition unless your doctor tells you to.

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

Things to be careful of

Sildenafil can cause dizziness and effects on vision. You should be aware of how you react to sildenafil before you drive or operate machinery.

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
- stuffy nose or hay fever
- muscle aches, back or limb pain
- swelling in limbs
- rash
- diarrhoea or upset stomach
- a numbness or tingling skin sensation
- breathlessness or coughing
- fever or flu like symptoms
- nose bleeds
- difficulty sleeping
- prolonged erection

Rarely men have lost eyesight sometime after taking such drugs as Sildenafil 25 mg, 50 mg or 100 mg tablets, Cialis or Levitra to treat impotence (known as erectile dysfunction). It is not known at this time if these medicines can cause vision loss.

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

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.

A small number of people have reported a loss of hearing, which may include a ringing or other persistent noise in the ears and dizziness, while taking sildenafil. It is not known whether hearing loss is related to sildenafil.

If you experience any loss of hearing, tell your doctor as soon as possible.

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 30°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

20 mg tablets

White to off white, round biconvex, film coated tablets, engraved "APO" on one side and "SIL" over "20" on the other side.

Bottles of 90 tablets:

AUST R 164808.

Blisters of 90 tablets:

AUST R 164810.

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

Ingredients

Each APO-Sildenafil PHT tablet contains 20 mg of sildenafil (as citrate) as the active ingredient. This medicine also contains the following:

- microcrystalline cellulose
- colloidal anhydrous silica
- croscarmellose sodium
- magnesium stearate
- hypromellose
- macrogol 8000
- titanium dioxide
- hypromellose

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

Sponsor

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