

APO-Sildenafil PHT

20 mg tablets

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 PHT Tablets. It contains the active ingredient sildenafil citrate.

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

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.

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

There is no evidence that this medicine is addictive.

Use in children

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

Before you 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**

These include 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:
 - Liver problems

- Recent stroke or heart attack
- A hereditary eye disorder called retinitis pigmentosa
- You have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION).
- **You are taking certain medicines used to treat fungal infections including ketoconazole and itraconazole.**
- **You are taking ritonavir, a treatment for HIV infection.**
- **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 previously had sudden loss of eyesight in one or both eyes.
3. You have or have had any medical conditions, especially the following:
 - heart or blood vessel problems
 - high blood pressure (BP greater than 170/110 mmHg) or you are being treated with certain blood pressure lowering medications
 - low blood pressure (BP less than 90/50 mmHg)
 - diabetes, especially if you also have eye 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
- pulmonary veno occlusive disease (blockage or narrow vein in the lung)
- any disease or deformity of your penis
- 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 receiving other treatments for pulmonary arterial hypertension
- previously experienced sudden decrease or loss of hearing
- previously experienced sudden vision loss

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

4. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
6. You are planning to have surgery or an anaesthetic.

7. You are currently receiving or are planning to receive dental treatment.
8. 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:

- 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
- an antibiotic called erythromycin
- ritonavir or saquinavir, medicine used to treat HIV infection
- cimetidine for stomach ulcers.

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

Other medicines not listed above may also interact with sildenafil.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They may also have a more

complete list of medicines to be careful with or avoid while taking sildenafil.

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

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 tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 for

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

Your doctor may want to reduce the dose gradually.

Make sure you have enough to last over weekends and holidays.

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 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. Seek medical attention urgently.

Tell your doctor that you are taking this medicine if:

- **you are about to start taking any new medicines, especially nitrates**

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

- 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 this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

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 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
- stuffy nose or hayfever
- 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.

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:

- Rarely men have lost eyesight some time 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.

If you lose sight in one or more eyes while taking Sildenafil PHT 20 mg tablets, 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.

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
- hayfever-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 PHT looks like

The 20 mg tablets are white to off-white, round, biconvex tablets, engraved "APO" on one side and "SIL" over "20" on the other side.

Ingredients

Each tablet contains 20 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 PHT 20 mg tablets

Bottles of 90 tablets: AUST R 164808

Blisters of 90 tablets: AUST R 164810

Sponsor

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This leaflet was last updated in September 2014.