

Sildenafil PHT APOTEX

(sildenafil (as citrate) 20 mg film coated tablets)

Consumer Medicine Information

What is in this leaflet

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking sildenafil 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 sildenafil PHT is used for

Sildenafil PHT is used to treat Pulmonary arterial HyperTension ("PHT" - high blood pressure in the blood vessels in the lungs). Sildenafil brings down the blood pressure by relaxing these vessels. This medicine contains the active ingredient sildenafil (present as sildenafil citrate) which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

Ask your doctor if you have any questions about why sildenafil has been prescribed for you.

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

Before you take sildenafil

When you must not take it

Do not take sildenafil 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 tradenames include tablets such as Anginine and Tridil; patches such as NitroDur, Nitradisc, TransidermNitro, Nitrocor, Nitroderm TTS and Minitran; sprays such as Nitrolingual and injections such as Nitronal.

Common tradenames for other nitrate preparations include tablets such as Imdur Durule, Sorbidin, Isordil, Carvasin, Corangin, ISMO 20, Imtrate, Coronex, Duride, Ikorel and Sodium Nitroprusside.

There may be other trade names not listed here.

2. **you are using amyl nitrite**
3. **you have suffered a heart attack or stroke in the last 6 months**
4. **you have severe liver problems**
5. **your blood pressure is unusually low and is not effectively treated**
6. **you have an eye disease called retinitis pigmentosa**
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 are taking certain medicines used to treat fungal infections including ketoconazole and itraconazole**
9. **you are taking ritonavir a treatment for HIV infection**
10. **you have an allergy to:**
 - sildenafil 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
11. **the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look all right**
12. **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 previously had sudden loss of eyesight in one or both eyes

You have any of the following medical conditions:

- you have heart or blood vessel problems
- you have high blood pressure
- 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 Viagra which contains the same active ingredient as in this medicine. Other medicines used to treat impotence include Cialis and Levitra
- you are receiving other treatments for your condition
- previously experienced sudden decrease or loss of hearing

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 should not breastfeed while taking sildenafil.

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

Taking other medicines

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

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

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

You may need to take different medicines or take different amounts of your medicine.

Also tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and sildenafil 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 that may be used to treat mild anxiety
- rifampicin used to treat leprosy or tuberculosis
- an antibiotic called erythromycin
- saquinavir a medicine used to treat HIV infection
- cimetidine for stomach ulcers

You may need to take different medicines or different amounts of your medicine. 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 this medicine 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

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 tablets at the same times each day.

Taking tablets at the same times each day will have the best effect. It will also help you to remember when to take it. Tablets can be taken with or without food.

How long to take it

You must take this medicine every day.

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

If you forget to take it

If you forget to take this medicine, take a dose as soon as you remember, then continue to take your tablets at the usual times.

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

However, tell your doctor or nurse if you think that a dose has been forgotten.

If you take too much (Overdose)

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

Immediately telephone your doctor or Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort.

While you are taking this medicine

Things you must do

Stop taking this medicine if you have a loss of eyesight in one or both eyes.

Seek medical attention urgently. If you are about to start taking any new medicines, especially nitrates, tell your doctor and pharmacist that you are taking this medicine.

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

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

Things you must not do

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

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 this medicine.

Do not take this medicine to treat any other conditions unless your doctor says so.

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 this medicine 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 this medicine.

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 get any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness
- flushing
- indigestion
- stuffy nose
- changes in vision such as blurring, a blue colour to your vision or a greater awareness of light
- muscle aches, back or limb pain
- rash
- diarrhoea or upset stomach
- a numbness or tingling skin sensation
- breathlessness or coughing
- fever or flu like symptoms
- nose bleeds
- difficulty sleeping
- hayfever

Rarely men have lost vision in one or both eyes some time after taking drugs such as Viagra, 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 this medicine, 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 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 this medicine

Storage

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.

Keep this medicine in a dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep the tablets 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.

Disposal

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

Product description

What it looks like

Sildenafil PHT APOTEX 20 mg film coated tablets are white to off white, round shaped, biconvex, film-coated tablets, debossed with '20' on one side and plain on other side.

The tablets are available in blister packs containing 90 tablets in each box.

Ingredients

Active ingredient

- sildenafil 20 mg

Other ingredients

- microcrystalline cellulose
- calcium hydrogen phosphate
- croscarmellose sodium
- hypromellose
- magnesium stearate
- OPADRY II complete film coating system 31K58643 WHITE (which contains: hypromellose, titanium dioxide, lactose, glycerol triacetate)

Sildenafil PHT APOTEX:

AUST R 188717

Name and Address of the Sponsor:

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne VIC 3000

Date of first inclusion in the ARTG:

10 September 2012

Date of Revision:

31 October 2018