

Sildatio PHT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Sildatio PHT?

Sildatio PHT contains the active ingredient sildenafil (present as sildenafil citrate). Sildatio PHT is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). Sildatio PHT lowers the blood pressure by relaxing these blood vessels.

For more information, see Section [1. Why am I using Sildatio PHT?](#) in the full CMI.

2. What should I know before I use Sildatio PHT?

Do not use if you have ever had an allergic reaction to sildenafil or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Sildenafil PHT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sildenafil and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Sildenafil PHT?

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

More instructions can be found in Section [4. How do I use Sildenafil PHT?](#) in the full CMI.

5. What should I know while using Sildenafil PHT?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Sildenafil PHT.You must stop treatment with Sildenafil PHT if you have a loss of eyesight in one or both eyes, or have an erection that lasts more than 04 hours. Seek medical attention urgently.
Things you should not do	<ul style="list-style-type: none">Do not use drugs containing amyl nitrate (sometimes called "poppers") while you are on Sildenafil PHT.If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">If you experience changes in vision, or dizziness when on Sildatio PHT, you should not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">You may feel lightheaded if you drink alcohol while you are using Sildenafil PHT
Looking after your medicine	<ul style="list-style-type: none">Keep Sildenafil PHT tablets where children cannot reach it.Keep Sildenafil PHT in a cool, dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Sildenafil PHT?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice headache, dizziness, flushing, indigestion, stuffy nose, muscle aches, back or limb pain, rash, diarrhoea or upset stomach, a numbness or tingling sensation, breathlessness or coughing, fever or flu like symptoms, nose bleeds, difficulty sleeping, hayfever, prolonged erection.

If you lose sight in one or both eyes or experience changes in vision such as blurring, a blue colour to your vision or great awareness of light while on Sildatio PHT, seek medical attention urgently.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Sildatio PHT

Active ingredient(s): *Sildenafil (as citrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sildatio PHT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sildatio PHT.**

Where to find information in this leaflet:

- [1. Why am I using Sildatio PHT?](#)
- [2. What should I know before I use Sildatio PHT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Sildatio PHT?](#)
- [5. What should I know while using Sildatio PHT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Sildatio PHT?

Sildatio PHT contains the active ingredient sildenafil (present as sildenafil citrate). Sildenafil belongs to group of medicines called phosphodiesterase type 5 inhibitors.

Sildenafil PHT is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). Sildenafil lowers the blood pressure by relaxing these vessels.

Sildenafil PHT is not for use in children under 18 years of age.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I use Sildatio PHT?

Warnings

Do not use Sildatio PHT if:

- You are taking nitrite or nitrate medications.
- You are being treated for angina (chest pain), or other heart conditions with medicines called nitrates.

Nitrate medicines include glyceryl nitrate (also called nitroglycerine).

Common tradenames for glyceryl trinitrate tablets includes Anginine and Lycinat.

Common tradenames for glyceryl trinitrate patches include Nitro-Dur, Transiderm-Nitro, Nitroderm TTS and Minitran.

Common trade names for glyceryl trinitrate sprays include Nitrolingual and Glytrin.

Tradenames for glyceryl trinitrate injections include Glyceryl trinitrate concentrate and Glyceryl trinitrate.

Common tradenames for other nitrate preparations include Imdur Durules, Monodor Durules, Sorbidin, Isordil, Imtrate, Duride, Isomonit, Ikorel and Sodium Nitroprusside

There maybe other tradenames not listed here

- You are taking guanylate cyclase stimulators (GCS) such as Adempas (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.**
- you have blood pressure that is unusually low and is not effectively treated.**
- an eye disease called retinitis pigmentosa.**
- 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 allergic to sildenafil 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 or tongue which may lead to difficulty swallowing or breathing

- Always check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of tampering.**
- the expiry date on the pack has passed.**

Check with your doctor if you:

- have any allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- have previously had sudden loss of eyesight in one or both eyes.**
- have any of the following medical conditions:**

- heart or blood vessel problems
- high blood pressure or diabetes, especially if you also have eye problems or 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 or stomach ulcer
- a disease of the blood called sickle cell anaemia
- pulmonary veno-occlusive disease (blockage or narrow vein in the lung) or any disease or deformity of your penis or you are receiving any treatment for male erectile dysfunction (impotence) including Viagra which contains the same medicine, sildenafil, Sildenafil PHT. There are other tradenames for sildenafil containing medicines that are not listed here. Other medicines used to treat impotence include Cialis and Levitra
- you are receiving other treatments for your condition
- you previously experienced sudden decrease or loss of hearing.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Sildenafil PHT should not be used during pregnancy. Your doctor will discuss the risks with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed while being treated with Sildenafil PHT.

What if I am taking other medicines?

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

Do not use Sildenafil PHT if you are using nitrate medicines for angina.

Do not use Sildenafil PHT 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). You may need to take different medicines or take different amounts of your medicine.

Some medicines may interfere with Sildenafil PHT and affect how it works.

- 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 you are being treated with Sildenafil PHT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sildenafil PHT.

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

3. How do I use Sildenafil PHT?

How much to take / use

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

When to take / use Sildenafil PHT

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

How to take Sildenafil PHT

Swallow the Sildenafil PHT tablet whole with a full glass of water.

How long to take Sildenafil PHT

You must take Sildenafil PHT tablets every day. continue taking your medicine for as long as your doctor tells you.

If you forget to use Sildenafil PHT

Sildenafil PHT should be used regularly at the same time each day. If you miss your dose at the usual time, take a dose as soon as you remember, then continue to take your tablets at usual times.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Sildenafil PHT

If you think that you have used too much Sildenafil PHT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

4. What should I know while using Sildenafil PHT?

Things you should do

Call your doctor straight away if you:

- You must stop treatment with Sildenafil PHT 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 being treated with Sildenafil PHT.
- See "Before treatment with Sildenafil PHT" for a list of common nitrate medications.
- Tell any other doctors, dentists and pharmacists who are treating you that you are being treated with Sildenafil PHT.

Remind any doctor, dentist or pharmacist you visit that you are using Sildenafil PHT.

Things you should not do

- Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are on Sildenafil PHT.
- 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 being treated with Sildenafil PHT.
- Do not take or use Sildenafil PHT to treat any other conditions unless your doctor says so.
- Do not give Sildenafil PHT to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sildenafil PHT affects you.

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

- If you experience changes in vision, or dizziness, when on
- Sildenafil PHT, you should not drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

You may feel lightheaded if you drink alcohol while you are using Sildenafil PHT.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young 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 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

5. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Headache• Dizziness• Flushing• Indigestion• Stuffy nose• 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	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • Nose bleeds • Difficulty sleeping • Hayfever • Prolonged erection 	
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Serious side effects

Serious side effects	What to do
<p>Rarely men have lost vision in one or both eyes sometime after taking drugs such as Viagra, Cialis or Levitra to treat impotence (known as erectile dysfunction).</p> <p>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 being treated with Sildenafil PHT. It is not known whether hearing loss is related to Sildenafil PHT.</p>	<p>If you lose sight in one or both eyes or experience changes in vision such as blurring, a blue colour to your vision or a greater awareness of light while on Sildenafil PHT, seek medical attention urgently.</p> <p>If you experience any loss of hearing, tell your doctor as soon as possible</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

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

What Sildenafil PHT contains

Active ingredient (main ingredient)	Sildenafil ARTG No. 188711
Other ingredients	Cellulose microcrystalline

(inactive ingredients)	Calcium hydrogen phosphate Croscarmellose Magnesium stearate Opadry II – 31K58643 White (hypromellose, titanium dioxide, lactose monohydrate, triacetin) ARTG No. 107652
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What Sildenafil PHT looks like

Sildenafil PHT 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.

Who distributes Sildenafil PHT

Arrow Pharma Pty Ltd
15-17 Chapel St,
Cremorne, Victoria, 3121
Australia

This leaflet was prepared in July 2023.