

SILDENAFIL PHT ARX

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 SILDENAFIL PHT ARX?

SILDENAFIL PHT ARX contains the active ingredient sildenafil (present as sildenafil citrate). SILDENAFIL PHT ARX is used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs). SILDENAFIL PHT ARX lowers the blood pressure by relaxing these vessels. For more information, see Section [1. Why am I using SILDENAFIL PHT ARX?](#) in the full CMI.

2. What should I know before I use SILDENAFIL PHT ARX?

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 ARX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SILDENAFIL PHT ARX 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 ARX?

- The usual dose is one 20 mg tablet taken three times a day (taken 6-8 hours apart).
- SILDENAFIL PHT ARX is not for use in children under 18 years of age.

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

5. What should I know while using SILDENAFIL PHT ARX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SILDENAFIL PHT ARX.• You must stop treatment with SILDENAFIL PHT ARX if you have sudden vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes, or have an erection that lasts more than 4 hours. Seek medical attention urgently.
Things you should not do	<ul style="list-style-type: none">• Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are on SILDENAFIL PHT ARX.• ARX. 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 SILDENAFIL PHT ARX, 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 ARX.
Looking after your medicine	<ul style="list-style-type: none">• Keep SILDENAFIL PHT ARX tablets where children cannot reach it.• Keep SILDENAFIL PHT ARX tablets in a cool, dry place where the temperature stays below 25 °C.

For more information, see Section [5. What should I know while using SILDENAFIL PHT ARX?](#) 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 skin sensation, breathlessness or coughing, fever or flu like symptoms, nose bleeds, difficulty sleeping, hayfever, prolonged erection.

If you have sudden vision problems, 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 ARX, seek medical attention urgently.

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

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.

SILDENAFIL PHT ARX

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using SILDENAFIL PHT ARX. **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 SILDENAFIL PHT ARX.**

Where to find information in this leaflet:

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

1. Why am I using SILDENAFIL PHT ARX?

SILDENAFIL PHT ARX contains the active ingredient **sildenafil (present as sildenafil citrate)**. Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

SILDENAFIL PHT ARX is used to treat **pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs)**.

SILDENAFIL PHT ARX lowers the blood pressure by relaxing these vessels.

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 SILDENAFIL PHT ARX?

Warnings

Do not use SILDENAFIL PHT ARX if:

- you are taking nitrite or nitrate medications.
- you are being treated for angina (chest pain), or other heart conditions with medicines called nitrates. These are available in multiple dosage forms, such as tablets, patches, sprays and injections. Active ingredients in nitrate medicines include, but not limited to:
 - o glyceryl trinitrate (also called nitroglycerin)
 - o isosorbide mononitrate, isosorbide dinitrate
 - o nicorandil
 - o sodium nitroprusside.
- you are taking guanylate cyclase stimulators (GCS), such as 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.
- you have an eye disease called retinitis pigmentosa.
- you have sudden vision problems including 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:
 - o hives, itching or skin rash
 - o 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.

Before treatment with SILDENAFIL PHT ARX, 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 vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes.
- have any of the following medical conditions:
 - o heart or blood vessel problems
 - o high blood pressure
 - o diabetes, especially if you also have eye problems
 - o leukaemia (cancer of the blood cells)
 - o multiple myeloma (a cancer of the bone marrow)
 - o any bleeding disorder such as haemophilia or problems with nose bleeds
 - o stomach ulcer
 - o a disease of the blood called sickle cell anaemia
 - o pulmonary veno-occlusive disease (blockage or narrow vein in the lung)
 - o any disease or deformity of your penis
 - o you are receiving any treatment for male erectile dysfunction (impotence) which contains the same medicine, sildenafil, as SILDENAFIL PHT ARX. There are other tradenames for sildenafil containing medicines that are not listed here. Other medicines used to treat impotence include tadalafil and vardenafil.

- o you are receiving other treatments for your condition
 - o you previously experienced sudden decrease or loss of hearing.
- take any medicines for any other condition

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 ARX 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 ARX.

Use in children

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

3. 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 take SILDENAFIL PHT ARX if you are using nitrate medicines for angina.

Do not take SILDENAFIL PHT ARX if you are taking guanylate cyclase stimulators (GCS), such as riociguat.

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

These medicines include bosentan, epoprostenol or Iloprost.

Some medicines and SILDENAFIL PHT ARX 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 you are being treated with SILDENAFIL PHT ARX.

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 ARX.

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

4. How do I take SILDENAFIL PHT ARX?

Take SILDENAFIL PHT ARX 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.

How much to take SILDENAFIL PHT ARX

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

When to take SILDENAFIL PHT ARX

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

How to take SILDENAFIL PHT ARX

- Swallow the SILDENAFIL PHT ARX tablet whole with a full glass of water.

How long to take SILDENAFIL PHT ARX

- You must take SILDENAFIL PHT ARX tablets every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take SILDENAFIL PHT ARX

If you miss your dose at the usual time and 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 ARX

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

5. What should I know while using SILDENAFIL PHT ARX?

Things you must do

- **You must stop treatment with SILDENAFIL PHT ARX if you have sudden vision problems including blurred, decreased or distorted vision, objects appear smaller or further away than they are, changes to colour vision, loss of eyesight in one or both eyes, experience**

loss of hearing 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 riociguat, tell your doctor and pharmacist that you are being treated with SILDENAFIL PHT ARX.

See "Do not use SILDENAFIL PHT ARX" for a list of common nitrate medications.

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

Things you must not do

- Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are on SILDENAFIL PHT ARX.
- 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 ARX.
- Do not take or use SILDENAFIL PHT ARX to treat any other conditions unless your doctor says so.
- Do not give SILDENAFIL PHT ARX 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 ARX affects you.

SILDENAFIL PHT ARX can cause dizziness and effects on vision.

If you experience changes in vision, or dizziness, when on SILDENAFIL PHT ARX, 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 ARX.

Looking after your medicine

SILDENAFIL PHT ARX Tablets:

- Store below 25 °C.
- 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.

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 medicine.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking SILDENAFIL PHT ARX tablets or if the medicine has passed its expiry date, ask your pharmacist what to do with any left over.

Do not use this medicine after the expiry date.

6. 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 • nose bleeds • difficulty sleeping • hayfever • prolonged erection. 	<p>Tell your doctor or pharmacist if you notice any of the following and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Rarely men have lost vision in one or both eyes sometime after taking drugs such as sildenafil, tadalafil or vardenafil to treat impotence (known as erectile dysfunction). • 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 ARX. It is not known whether hearing loss is related to SILDANIL. 	<p>If you have sudden vision problems, lose sight in one or both eyes or experience changes in vision such as blurring, decreased or distorted vision, objects appear smaller or further away than they are, changes to your colour vision, a blue colour to your vision or a greater awareness of light while on</p>

	<p>SILDENAFIL PHT ARX, seek medical attention urgently. If you experience any loss of hearing, tell your doctor as soon as possible.</p>
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Who distributes SILDENAFIL PHT ARX

Arrotex Pharmaceuticals Pty Ltd
 15 – 17 Chapel Street
 Cremorne VIC 3121
www.arrotex.com.au

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Tell your doctor 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.

7. Product detail

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

What SILDENAFIL PHT ARX tablet contains

Active ingredient (main ingredient)	sildenafil (as citrate) equivalent to 20 mg sildenafil per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • calcium hydrogen phosphate • croscarmellose sodium • magnesium stearate • OPADRY II complete film coating system 31K58643 WHITE (ID 107652)
Potential allergens	lactose

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

What SILDENAFIL PHT ARX tablet looks like

SILDENAFIL PHT ARX tablets are white to off-white, round biconvex film coated tablets, debossed with "20" on one side and plain on the other side (AUST R 188717).

Available in blister packs containing 90 tablets in each box.

Who is the sponsor of SILDENAFIL PHT ARX

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