

# Vasafil

## 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 Vasafil?

Vasafil contains the active ingredient sildenafil citrate. Vasafil is used to treat erectile dysfunction also commonly called impotence in men.

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

### 2. What should I know before I use Vasafil?

Do not use if you have ever had an allergic reaction to sildenafil citrate 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 Vasafil?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with sildenafil citrate 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 Vasafil?

- The dose varies from patient to patient. Your doctor will decide the correct dose for you depending on your condition and response.
- Your doctor may instruct you to take one 25mg tablet a day or one 50mg tablet a day or one 100mg tablet a day.

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

### 5. What should I know while using Vasafil?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using Vasafil.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctors know you are taking Vasafil.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machine or tools until you know how Vasafil affects you</li><li>• If you experience changes in vision, or dizziness, when taking VASAFIL, you should not drive or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• If you are affected by alcohol, your ability to get and maintain an erection can be affected.</li><li>• Do not drink large amounts of alcohol before sexual activity</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Vasafil in a locked cupboard where children cannot reach it.</li><li>• Keep your tablets in cool dry place where temperature stays below 25°C</li></ul>

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

### 6. Are there any side effects?

The common side effects include headache, dizziness, flushing, indigestion, nasal congestion, diarrhoea, rash, dry mouth, throat, nose, or eye. Other side effects include unusual heartbeat, urinary tract infection (stinging or burning urine, more frequent need to pass urine), blood in the urine, changes in vision such as blurring, a blue color to your vision or a greater awareness of light, persistent headache or fainting, bleeding from nose, pain or tingling in your hands, toes or feet, decreased sensitivity or numbness in your mouth, Irritation or pain in or around eyes, signs of allergy such as shortness of breath

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.

# Vasafil

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

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Vasafil. **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 Vasafil.**

Where to find information in this leaflet:

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

## 1. Why am I using Vasafil?

Vasafil contains the active ingredient **sildenafil (as citrate)**. Vasafil belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

**Vasafil is used to treat erectile dysfunction, also commonly called impotence in men. This is when a man cannot get, or keep, a hard erect penis, suitable for sexual activity.**

It works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.

Vasafil will work only if you are sexually excited. It will not increase your sex drive. It is not for use in women.

It is available only with a doctor's prescription.

## 2. What should I know before I use Vasafil?

### Warnings

**Do not use Vasafil if:**

- You are allergic to sildenafil citrate, or any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing wheezing or shortness of breath.
- Always check the ingredients to make sure you can use this medicine.

- You must not take vasafil if you are taking any nitrate medication. It may lead to a severe drop in your blood pressure, which may be difficult to treat.
- Because sexual activity may place a strain on your heart, your doctor will need to check whether you are fit enough to take Vasafil.
- Do not take vasafil 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 nitroglycerine). Common trade names include tablets, such as Anginine, Lycinate and Nitrostat; patches such as Nitro-Due, Traniderm-Nitro, NitrodermTTS and Minitran; sprays such as Nitrolingual and Glytrin and injections such as Glycerine 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.

- Do not take VASAFIL if you are using amyl nitrate.
- Do not take Viagra if 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).

**Do not take it if you have:**

- Heart or blood vessel problems that make sexual intercourse advisable.
- Suffered a heart attack or stroke in the last 06 months.
- Have severe liver problems.
- Unusually high or low blood pressure that is not effectively treated.
- You have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischemic optic neuropathy (NAION).
- An eye disease called retinitis pigmentosa.

Do not take VASAFIL if the expiry date (Exp.) printed on the pack has passed.

Do not take VASAFIL if the packaging is torn or shows signs of tampering.

hypertension including Tracleer (bosentan) or Revatio which also contains sildenafil

### Check with your doctor if you:

- have any other medical conditions, allergies to any other medicines, foods, dyes or preservatives.
- Have any other heart or blood vessel problems.
- Have previously had sudden loss of eyesight in one or both eyes.

### If any medical condition, especially the following:

- Diabetes, especially if you also have eye problems.
- Kidney or liver problems
- Leukemia (cancer of the blood cells)
- Multiple myeloma (a cancer of the bone marrow)
- Any disease or deformity of your penis
- Any bleeding disorder such as haemophilia
- Stomach ulcer
- A disease of the blood called sickle cell anaemia.
- Color vision problems
- Previous experience of a sudden decrease or loss of hearing
- Are taking any medicines to treat high blood pressure in the vessels of lungs (pulmonary arterial hypertension) including Tracleer (bosentan) or Revatio which also contains sildenafil.

**Tell your doctor if you are receiving any other treatment for impotence.**

**If you have not told your doctor about any of the above, tell them before you start taking VASAFIL.**

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?](#)

### 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.

Some medicines may be affected by VASAFIL, or may affect how well it works. These include:

- Cimetidine , a medicine used to treat ulcers
- Some medicines used to treat fungal infections including ketoconazole and itraconazole
- Some antibiotics including erythromycin and rifampicin
- Some protease inhibitors such as ritonavir and saquinavir for the treatment of HIV infections
- Medicine called alpha-blockers, that are used to treat high blood pressure or prostate problems.
- Medicine used to treat high blood pressure in the blood vessels in the lungs (pulmonary arterial

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

### 4. How do I use Vasafil?

#### How much to take / use

- The dose varies from patient to patient.
- Your doctor will decide the correct dose for you depending on your condition and response.
- Your doctor may instruct you to take one 25mg tablet a day or one 50mg tablet a day or one 100mg tablet a day.

**Do not take more than one dose of VASAFIL a day.**

**Follow all directions given to you by your doctor and pharmacist carefully.**

#### When to take / use Vasafil

**Take your dose of VASAFIL about one hour before you intend to have sex.**

**Swallow the tablets with a glass of water.**

**The amount of time it takes to start working varies from person to person, but it normally takes between half an hour and one hour.**

You may find Vasafil takes longer to work if you take it with or soon after a heavy meal.

**VASAFIL will work only if you are sexually excited.**

#### If you use too much VASAFIL

If you think that you have used too much VASAFIL, 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.**

### 5. What should I know while using VASAFIL?

#### Things you should do

### Call your doctor straight away if you:

- See “Before you take VASAFIL” for a list of common nitrate medications. You should not take it if you are taking any of the medications on the list.

**Stop using it if you have a loss of eyesight in one or both eyes, experienced loss of hearing or have an erection that persists more than 4 hours. Seek medical attention urgently.**

**If it does not help you get an erection or if your erection does not last long enough to complete sexual intercourse, tell your doctor.**

**In this case, your doctor may decide that you need a higher dose.**

**Remind any doctor, dentist, or pharmacist you visit that you are using VASAFIL.**

### Things you should not do

If you get an angina attack do not take nitrate medicines to relieve the pain but tell your doctor immediately. Make sure your doctors know you are taking Vasafil.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how VASAFIL affects you.**

If you experience changes in vision, or dizziness, when taking VASAFIL, you should not drive or operate machinery.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you are affected by alcohol, your ability to get and maintain an erection can be affected.

**Do not drink large amounts of alcohol before sexual activity.**

### Looking after your medicine

**Keep VASAFIL where children cannot reach it.**

- **A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.**
- **Keep your tablets in a cool dry place where the temperature stays below 25°C.**

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.

### When to discard your medicine

#### 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.

## 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"><li>• <b>Headache, dizziness</b></li><li>• Flushing</li><li>• Indigestion</li><li>• Nasal congestion</li><li>• Diarrhoea</li><li>• Rash</li><li>• Dry mouth, throat. Nose or eye</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Unusual heartbeat</li><li>• Urinary tract infection (stinging or burning urine, more frequent need to pass urine)</li><li>• Blood in the urine</li><li>• Changes in vision such as blurring, a blue colour to your vision or a greater awareness of light.</li><li>• Persistent headache or fainting</li><li>• Bleeding from the nose</li><li>• Pain or tingling in your hands, toes or feet.</li><li>• Decreased sensitivity or numbness in your mouth</li><li>• Irritation or pain in or around eyes</li><li>• Signs of allergy such as shortness of breath, wheezing or difficulty Breathing; swelling of the face, lips, tongue or other parts</li><li>• Chest pain</li><li>• Sudden decrease or loss of hearing</li><li>• Seizures, fits or convulsions.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Very rarely your erection may persist for longer than usual. If your erection continues for four hours, or sooner if there is pain, you should seek medical attention urgently.**

**Rarely men have lost eyesight some time after taking drugs to treat erectile dysfunction (known as impotence). It is not known at this time if VASAFIL causes this. If you lose eyesight in one or more eyes, seek medical attention urgently.**

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

**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](http://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 details**

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

### **What VASAFIL contains**

<b>Active ingredient (main ingredient)</b>	Sildenafil (as citrate)
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Calcium hydrogen phosphate Croscarmellose sodium Magnesium stearate Opadrry II 85F60888 Blue (ARTG 106662)
<b>Potential allergens</b>	n/a

**The tablet does not contain gluten or lactose.**

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

### **What VASAFIL looks like**

Vasafil comes IN 3 strengths of tablets.

- VASAFIL 25 – green coloured, round film-coated tablet with a break line on one side
- VASAFIL 50 – green coloured, round film-coated tablet with a cross break line on one side
- VASAFIL 100 – green coloured, round film-coated tablet with a cross break line on one side

All strengths come in packs of 4 tablets. VASAFIL 100 also comes in a pack of 12 tablets.

Australian registration numbers:

VASAFIL 25 - AUST R 172073

VASAFIL 50 - AUST R 172074

VASAFIL 100 – AUST R 172068

### **Who distributes VASAFIL**

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

This leaflet was prepared in August 2023.