

# VEDAFIL®

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I taking VEDAFIL?

VEDAFIL contains the active ingredient sildenafil. VEDAFIL is used to treat erectile dysfunction, more commonly known as impotence, in men. For more information, see Section [1. Why am I taking VEDAFIL?](#) in the full CMI.

### 2. What should I know before I take VEDAFIL?

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

**Talk to your doctor if you have any other medical conditions or take any other medicines.** For more information, see Section [2. What should I know before I take VEDAFIL?](#) in the full CMI.

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

Some medicines may interfere with VEDAFIL 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 take VEDAFIL?

- Take VEDAFIL exactly as your doctor has prescribed.
- Your doctor will decide the correct dose for you depending on your condition and response.

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

### 5. What should I know while taking VEDAFIL?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking VEDAFIL.
- Stop taking VEDAFIL if you have a loss of eyesight in one or both eyes, experience loss of hearing or have an erection that persists for more than 4 hours. Seek medical attention urgently.

	<ul style="list-style-type: none"> <li>● If you are about to start taking any new medicines, especially nitrates, or riociguat, tell your doctor and pharmacist that you are taking VEDAFIL.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are taking VEDAFIL.</li> <li>● If you get an angina attack, do not take nitrate medicines to relieve the pain but tell your doctor immediately.</li> <li>● Do not give VEDAFIL to anyone else, even if they have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● If you experience changes in vision, or dizziness when taking VEDAFIL, you should not drive or operate machinery.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Be careful drinking alcohol while taking VEDAFIL.</li> </ul>

### Looking after your medicine

- Keep VEDAFIL in a cool, dry place where the temperature stays below 25°C.
- Keep this medicine where children cannot reach it.

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

## 6. Are there any side effects?

**Tell your doctor or pharmacist if you notice any of the following and they worry you:** headache, dizziness, flushing, hot flushes, indigestion, heartburn, nasal or sinus congestion, swelling of your nose, diarrhoea, rash, tightness in your throat, feeling hot or irritable, redness in your mouth or tongue. **Tell your doctor or go straight to the Emergency Department if you notice any of the following:** unusual heartbeat, persistent headache or fainting, bleeding from the nose, pain or tingling in your hands, toes or feet, red eye(s), swollen, puffy or pain in or around the eye(s), blood in the urine, changes to your normal vision, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, chest pain, increased heart rate, seizures, fits or convulsions or your erection is increased, painful or persists for longer than four hours.

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.

# VEDAFIL®

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

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I taking VEDAFIL?

**VEDAFIL contains the active ingredient sildenafil (as citrate).** VEDAFIL belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

**VEDAFIL is used to treat erectile dysfunction, more commonly known as 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.

VEDAFIL will not increase your sex drive and will work only if you are sexually excited.

VEDAFIL is not for use in women.

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

## **2. What should I know before I take VEDAFIL?**

### **Warnings**

**YOU MUST NOT TAKE VEDAFIL IF YOU ARE TAKING NITRATES OR NITRITE MEDICATIONS, USED TO TREAT ANGINA (CHEST PAIN) OR OTHER HEART CONDITIONS. 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 VEDAFIL.**

## Do not take VEDAFIL if:

- 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 or other parts of the body
  - shortness of breath
- wheezing or difficulty breathing

Always check the ingredients to make sure you can take this medicine.

- **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 are not limited to:**
  - glyceryl trinitrate (also called nitroglycerin)
  - isosorbide mononitrate, isosorbide dinitrate
  - nicorandil
  - 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 or CTEPH) or narrowing of



the vessels that carry blood from the heart to the lungs (pulmonary arterial hypertension or PAH).

- **you have heart or blood vessel problems that make sexual intercourse inadvisable**
  - **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 high or low or is not effectively treated**
  - **you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION)**
  - **you have an eye disease called retinitis pigmentosa**
  - **you are taking amyl nitrate (sometimes called 'poppers')**
  - **the packaging is torn or shows signs of tampering, or does not look quite right even if the tablets may look alright**
  - **the expiry date on the pack has passed**
- If it has expired or is damaged, return it to your pharmacist for disposal.

### **Check with your doctor if you:**

- **have any allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- **have any other heart or blood vessel problems**

- **have previously had sudden loss of eyesight in one or both eyes**
- **have any of the following medical conditions:**
  - diabetes, especially if you also have eye problems
  - kidney or liver problems
  - leukaemia (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
  - colour vision problems
  - previously experienced sudden decrease or loss of hearing
- **are taking or using any other treatment for impotence**
- **are taking any medicines to treat high blood pressure in the vessels of the lungs (pulmonary arterial hypertension) including bosentan or Revatio which also contains sildenafil.**

**Tell your doctor if you have any other medical conditions.**

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

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.

**Do not take VEDAFIL if you are taking or using nitrate medicines for angina.**

**Do not take VEDAFIL if you are taking guanylate cyclase stimulators (GCS), such as riociguat.**

Some medicines and VEDAFIL may interfere with each other. 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 infection
- medicines called alpha-blockers. These are used to treat high blood pressure or prostate problems
- bosentan, a medicine used to treat high blood pressure in the vessels of the lungs.

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

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

## **4. How do I take VEDAFIL?**

Take VEDAFIL 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 box, ask your doctor or pharmacist for help.

### **How much to take**

- Your doctor will decide the correct dose for you depending on your condition and response.
- This can be either one 25 mg tablet, one 50 mg tablet, or one 100 mg tablet per day.
- **Do not take more than one dose of VEDAFIL a day.**

### **How to take it**

Swallow the tablet whole with a full glass of water.

### **When to take VEDAFIL**

- Take your dose of VEDAFIL about one hour before you intend to have sex.

- The amount of time VEDAFIL takes to start working varies from person to person, but it normally takes between half an hour and one hour.
- You may find VEDAFIL takes longer to work if you take it with a heavy meal.
- VEDAFIL will work only if you are sexually excited.

## **If you take too much VEDAFIL**

If you think that you or anyone else may have taken too much VEDAFIL, urgent medical attention may be needed.

### **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 taking VEDAFIL?**

### **Things you should do**

- **Stop taking VEDAFIL if you have a loss of eyesight in one or both eyes, experience loss of hearing or have an erection that persists for more than 4 hours. Seek medical attention urgently.**

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

In these cases, your doctor may decide that you need a higher dose.

- **If you are about to start taking any new medicines, especially nitrates, or riociguat, tell your doctor and pharmacist that you are taking VEDAFIL. See "[2. What should I know before I take VEDAFIL?](#)" for a list of common nitrate medications.**

- **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

- **Tell any other doctors, dentists and pharmacists who are treating you that you are taking VEDAFIL.**

## **Things you should not do**

- Do not take VEDAFIL to treat any other complaints unless your doctor tells you to.
- **Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are taking VEDAFIL.**
- **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 VEDAFIL.**

- **Do not give VEDAFIL to anyone else, even if they have the same condition as you.**

## **Driving or using machines**

**Be careful before you drive or take any machines or tools until you know how VEDAFIL affects you.**

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

## **Drinking alcohol**

**Be careful drinking alcohol while taking VEDAFIL.**

Drinking alcohol can temporarily impair the ability to get an erection.

Do not drink large amounts of alcohol before sexual activity.

## **Looking after your medicine**

- 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 medicines.

## **Getting rid of any unwanted medicine**

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

Do not take this medicine after the expiry date.

## **6. Are there any side effects?**

While VEDAFIL helps most people, it can cause some unwanted side effects in a few people. 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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VEDAFIL.

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

Do not be alarmed by this list of possible side effects.

**You may not get any of them.**



## Less serious side effects

Less serious side effects	What to do
<p><b>Nervous system related:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• dizziness</li></ul> <p><b>Vascular related:</b></p> <ul style="list-style-type: none"><li>• flushing</li><li>• hot flushes</li></ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"><li>• indigestion, an uncomfortable feeling in the stomach or belching after eating</li><li>• heartburn</li><li>• diarrhoea</li><li>• dry mouth or dry throat</li></ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"><li>• nasal congestion</li><li>• sinus congestion</li><li>• dry nose</li></ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"><li>• rash</li></ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"><li>• dry eyes</li></ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p> <p>This list includes the more common side effects of your medicine.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Other side effects:</b></p> <ul style="list-style-type: none"> <li>● swelling of your nose</li> <li>● tightness in your throat</li> <li>● feeling hot or irritable</li> <li>● redness in your mouth or tongue</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>● fast or unusual heartbeat</li> </ul> <p><b>Urogenital related:</b></p> <ul style="list-style-type: none"> <li>● urinary tract infection (stinging or burning urine, more frequent need to pass urine)</li> <li>● blood in the urine</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>● persistent headache or fainting</li> <li>● pain or tingling in your hands, toes or feet</li> </ul>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p> <p>This list includes serious side effects that may require medical attention.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● decreased sensitivity or numbness in your mouth</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>● irritation or feeling of having something in the eye</li> <li>● swollen or puffy eye(s)</li> <li>● fatigue, pain in or around the eyes</li> <li>● "red eye" due to swollen blood vessels in the white part of the eye and in the eyelids</li> </ul> <p><b>Other side effects:</b></p> <ul style="list-style-type: none"> <li>● bleeding from the nose</li> </ul>	

### **More serious side effects**

<b>More serious side effects</b>	<b>What to do</b>
<p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath</li> <li>● wheezing or difficulty breathing</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects.</b></p>

<b>More serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● swelling of the face, lips, tongue or other parts of the body</li> <li>● skin rash, itching or hives</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>● chest pain, an uncomfortable feeling in the chest (often spreading to the arms, neck and sometimes to the shoulders and back) or a feeling of tightness, pressure or heaviness in the chest</li> <li>● increased heart rate</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>● seizures, fits or convulsions</li> </ul> <p><b>Urogenital related:</b></p> <ul style="list-style-type: none"> <li>● your erection is increased, painful or persists for longer than usual</li> </ul> <p>If your erection continues for four hours, or sooner if there is pain, you</p>	<p>This list includes very serious side effects. You may need urgent medical attention or hospitalisation.</p> <p>These side effects are very rare.</p>

<b>More serious side effects</b>	<b>What to do</b>
<p>should seek medical attention urgently.</p> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>● Changes to your normal vision such as: <ul style="list-style-type: none"> <li>○ red or yellow colour tinges to your vision or colourless objects appear coloured</li> <li>○ you see a halo around lights, sparks or lights when your eyes are closed</li> </ul> </li> </ul> <p>Rarely, men have lost eyesight after taking drugs to treat erectile dysfunction. If you lose eyesight 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, seek medical attention urgently.</p> <p><b>Other side effects:</b></p>	

<b>More serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• sudden decrease or loss of hearing</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell or if you don't understand anything in this list.**

This is not a complete list of all possible side effects. 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 VEDAFIL contains

<b>Active ingredient (main ingredient)</b>	sildenafil (as citrate) equivalent to 25 mg, 50 mg or 100 mg sildenafil
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• calcium hydrogen phosphate anhydrous</li><li>• croscarmellose sodium</li><li>• magnesium stearate</li><li>• OPADRY complete film coating system 03K80846 BLUE (ARTG PI No: 106239)</li></ul>
<b>Potential allergens</b>	N/A

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

## What VEDAFIL looks like

25 mg - blue film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 25' on other side. (AUST R 162807)

50 mg - blue film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 50' on other side. (AUST R 162805)

100 mg - blue film-coated, round biconvex tablets debossed with 'M' on one side and 'SL over 100' on other side. (AUST R 162806)

All strengths are available in a box of 4 tablets. The 100 mg tablets are also available in a box of 12 tablets.

## **Who distributes VEDAFIL**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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VEDAFIL® is a Viatris company trade mark

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