

# AZULVIG™

sildenafil (as citrate) 25 mg/mL oral suspension

## 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 AZULVIG?

AZULVIG contains the active ingredient sildenafil (as citrate) 25 mg/mL. AZULVIG is used to treat erectile dysfunction, more commonly known as impotence, in men. For more information, see Section [1. Why am I using AZULVIG?](#) in the full CMI.

### What should I know before I take AZULVIG?

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

### What if I am taking other medicines?

Some medicines may interfere with AZULVIG 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.

### How do I take AZULVIG?

- Take AZULVIG exactly as your doctor has prescribed.
  - Your doctor will decide the correct dose for you depending on your condition and response.
  - The possibility to adjust the dose according to comorbidities, tolerability and efficacy for each patient, is an important feature of a sildenafil-containing pharmaceutical dosage form. AZULVIG is a prescription medicinal product and therefore the doctor could prescribe you the most adequate dose taking into account your particular characteristics. AZULVIG allows the doctor to adjust to the lowest possible effective dose using the same product and facilitates the titration/flexibilization of the dose, in case it is required by the patient, and according to medical criteria. This also allows to minimize the adverse events.
  - The goal of the doctor is to find the ideal dose, sufficient to gain the appropriate pharmacological effect, but as low as possible to minimize adverse effects.
- More instructions can be found in Section [4. How do I take AZULVIG?](#) in the full CMI.

### 2. What should I know while using AZULVIG?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist or other health professionals who are treating you that you are taking AZULVIG.</li><li>• Stop taking AZULVIG if you have a loss of eyesight in one or both eyes, experience loss of hearing or have an erection that persists more than 4 hours. Seek medical attention urgently.</li><li>• If you are about to start taking any new medicines, especially nitrates, or riociguat, tell your doctor and pharmacist that you are taking AZULVIG.</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 AZULVIG.</li><li>• If you get an angina attack, do not take nitrate medicines to relieve the pain but tell your doctor immediately.</li><li>• You must not give AZULVIG 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 AZULVIG, 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 AZULVIG.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep AZULVIG in a cool, dry place where the temperature stays below 30°C.</li><li>• Keep this medicine where children cannot reach it.</li></ul>

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

### 3. 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, 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.

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# AZULVIG™

Active ingredient(s): *sildenafil (as citrate) 25 mg/mL oral suspension*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

### 1. Why am I using AZULVIG?

AZULVIG contains the active ingredient **sildenafil (as citrate) 25 mg/mL as oral suspension**.

AZULVIG belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors.

AZULVIG 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.

AZULVIG will work only if you are sexually excited.

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

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

#### Warnings

YOU MUST NOT TAKE AZULVIG IF YOU ARE TAKING NITRATES OR NITRITE MEDICATIONS OR SUBSTANCES. THIS COMBINATION 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 AZULVIG.

#### Do not take AZULVIG 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 which may lead to difficulty swallowing or 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**

Nitrate medicines include glyceryl trinitrate (also called nitroglycerin) which are available in multiple dosage forms such as tablets, patches, sprays and injections.

- **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**
- **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 difficulty swallowing, a diagnosis of dysphagia, and/or require fluids, food, or any other thickening agent to assist with swallowing your medications.**
- **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 AZULVIG.**

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

## 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 AZULVIG if you are taking or using nitrate medicines for angina.**

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

Some medicines and AZULVIG 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 AZULVIG.

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

## How do I use AZULVIG?

Take AZULVIG 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 / use

- **Use strictly the exact number of pump strokes of AZULVIG prescribed for you- No more, no less (see table 1 below).**

*Table 1: Usual recommended doses*

Number of pump strokes	Volume of suspension	Dose (quantity of sildenafil)
2	1 mL	25 mg
4	2 mL	50 mg

- **The usual starting dose is 4 pump strokes** (2 mL of suspension or 50 mg sildenafil), although some patients may start with 2 pump strokes (1 mL of suspension).
- Each pump stroke delivers 0.5mL of suspension (containing 12.5 mg of sildenafil).
- **The maximum daily dose is 4 pump strokes** (2 mL of AZULVIG suspension, or 50 mg sildenafil) in 24 hours.

### How to take / use

Always take AZULVIG exactly as advised by your doctor and/or pharmacist. Check with your doctor or pharmacist if you are not sure.

**Take your dose by placing the prescribed quantity number of AZULVIG pumps onto the center, top of your tongue, then immediately swallow the whole dose with saliva.**

**Do not pump AZULVIG suspension onto the inside of your cheeks, or underneath your tongue or on the edges of your tongue.**

Do not snack, chew gum or eat a meal at the same time as using AZULVIG suspension.

## When to take / use AZULVIG

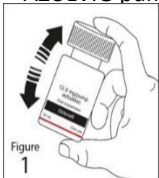
- Take your dose of AZULVIG about one hour before you intend to have sex.
- The amount of time AZULVIG takes to start working varies from person to person, but it normally takes between half an hour and one hour.
- You may find AZULVIG takes longer to work if you take it with a heavy meal.
- AZULVIG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

## How to use AZULVIG pump bottle

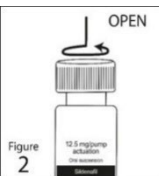
### Before use

AZULVIG can deliver 10 accurate 25 mg doses or 8 accurate 50 mg doses if used as indicated in these instructions. You should discard the product after taking this number of doses. In case your doctor has prescribed you different doses and you have taken both 25 mg doses and 50 mg doses using the same bottle, do not use the product if the remaining suspension is below the red line on the bottle. In both cases discard the product appropriately and safely with the child-resistant cap in place as accordance with advice in "Getting rid of any unwanted medicine" under "5. What should I know while using AZULVIG."

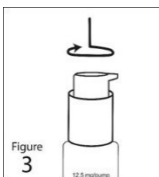
Follow the 10 steps below for the correct use of AZULVIG pump bottle:



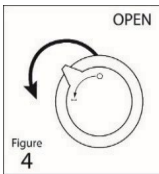
1. Shake the bottle vigorously for approximately 20 seconds with the metering pump in closed position to ensure that no drug precipitate is observed in the bottom of the bottle before each use. See figure 1.



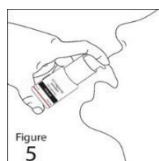
2. The child-resistant screw cap should be removed by pushing it down firmly and turning it anticlockwise. See figure 2.



3. Place the dosage pump on top of the bottle by sliding the plastic dip tube carefully into the bottle. The dosage pump then needs to be placed onto the neck of the bottle and screwed clockwise until it is firmly attached. See figure 3.

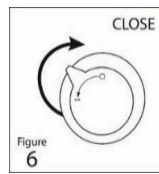


4. Twist the head of the dosage pump into open position. See figure 4.

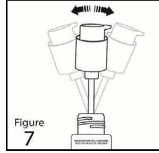


5. Before every use (including first-time use): Activate the pump three times to prepare (prime) the dosage pump. Discard any product released during this activation into an absorbent material. The pump is now ready to be used and each metered spray delivers an average of 12.5 mg of sildenafil. A failure to this priming process may lead to a lower when used.

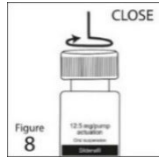
6. Tilt your head back a little. Place the dosage pump in your mouth. Press the dosage pump as many times as required, according to the dose prescribed by your doctor and apply the suspension on the tongue and swallow the suspension immediately with saliva. Avoid direct



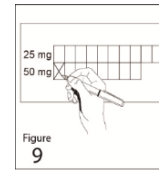
contact between the end of the dosage pump and inside the mouth and tongue. Swallow it immediately with saliva. (See figure 5).



7. Twist the dosage pump to closed position (figure 6) and remove the pump after dripping it against the internal wall of the bottle by unscrewing anticlockwise (figure 7).

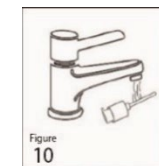


8. The child resistant screw cap should be put back on the bottle to close it immediately after each use (See figure 8).

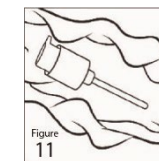


9. Securely replace the child resistant screw cap onto the bottle immediately after each use. (See figure 8).

10. Mark the checkbox on the bottle box to keep track of the number of doses. (See figure 9).



The quantity of current AZULVIG contents is visible through the translucent bottle container.



11. Thoroughly wash the dosage pump with water and ensure that no product or water remains in the dosage pump by activating it several times over an absorbent material. Allow it to dry completely before the next use. (See figure 10 and figure 11).

Store this medicine out of the sight and reach of children.

**Follow these instructions and do not store the product with the dosage pump as the closure to avoid any risk of accidental intake by children.**

## If you forget to use AZULVIG

AZULVIG should be used exactly as prescribed by your doctor. Check with your doctor if you forget to use AZULVIG.

**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 AZULVIG

If you think that you have used too much AZULVIG, 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 AZULVIG?

### Things you should do

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

If AZULVIG 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 AZULVIG.
- See "[2. What should I know before I take AZULVIG?](#)" for a list of common nitrate medications.
- Tell any other doctors, dentists and pharmacists who are treating you that you are taking AZULVIG.

### Things you should not do

- Do not use drugs containing amyl nitrite (sometimes called "poppers") while you are taking AZULVIG.
- 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 AZULVIG.
- Do not give AZULVIG 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 AZULVIG affects you.

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

### Drinking alcohol

Be careful drinking alcohol while taking AZULVIG.

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 30°C
  - Keep AZULVIG in their pack until it is time to take them. If you take AZULVIG 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 meters (5 feet) above the ground is a good place to store medicines.

### 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.

Do not use 12 months after first opening.

## 6. Are there any side effects?

While AZULVIG 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.

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

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</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>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>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>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> <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>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>

## More serious side effects

More serious side effects	What to do
<p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>shortness of breath</li> <li>wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>chest pain</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 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</li> </ul> </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>

<p>to your vision or colourless objects appear coloured</p> <ul style="list-style-type: none"> <li>you see a halo around lights, sparks or lights when your eyes are closed</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> <ul style="list-style-type: none"> <li>sudden decrease or loss of hearing</li> </ul>	
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**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 AZULVIG contains

<b>Active ingredient (main ingredient)</b>	Sildenafil (as citrate) equivalent to 25 mg sildenafil
<b>Other ingredients (inactive ingredients)</b>	Sodium Benzoate Citric Acid Sucralose Acesulfame potassium (E-950) Hypromellose Xanthan Gum Peppermint flavour (PI 109068) Masking flavour (PI 111611) Purified Water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

### **What AZULVIG looks like**

AZULVIG 25 mg/mL is a white to off-white oral suspension, with a characteristic mint odour. It is available in 30 mL plastic bottles, with a plastic pump nozzle which dispenses 0.5 mL of suspension per pump stroke. (Aust R 407839).

### **Who distributes AZULVIG**

#### **Sponsor**

AdiraMedica Pty Ltd

Level 1, 441 South Road

Bentleigh VIC 3204.

This leaflet was prepared in April 2024.

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