

## 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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being given IZERVAY?

IZERVAY contains the active ingredient avacincaptad pegol. IZERVAY is used to treat adult patients with an eye condition called geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

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

### 2. What should I know before I am given IZERVAY?

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

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

Some medicines may interfere with IZERVAY 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 will I be given IZERVAY?

- IZERVAY is injected directly into the eye by your doctor.
- You will be treated with one injection every month for the first year, and every month or every other month thereafter.
- The recommended dose is 2 mg (0.1 ml) avacincaptad pegol.

More instructions can be found in Section [4. How will I be given IZERVAY?](#) in the full CMI.

### 5. What should I know while being given IZERVAY?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are receiving IZERVAY.</li><li>• Tell your doctor if you experience signs of inflammation or infection.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• IZERVAY may cause blurred vision in some people. You should not drive or use machinery until your eyesight has recovered.</li><li>• Be careful before you drive or use any machines or tools until you know how IZERVAY affects you.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Your ophthalmologist (eye doctor) will treat you with IZERVAY. You will not be asked to store this medicine at home.</li></ul>

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

### 6. Are there any side effects?

IZERVAY can cause side effects related to your eye, such as bleeding, pain, irritation or changes in your vision.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

#### **WARNING: NEOVASCULAR (WET) AMD**

Wet AMD is a serious and vision threatening condition that is associated with IZERVAY. Wet AMD requires urgent eye specialist review and treatment.

# IZERVAY™

Active ingredient: *avacincaptad pegol*

## Consumer Medicine Information (CMI)

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

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

1. [Why am I being given IZERVAY?](#)
2. [What should I know before I am given IZERVAY?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given IZERVAY?](#)
5. [What should I know while being given IZERVAY?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I being given IZERVAY?

IZERVAY contains the active ingredient **avacincaptad pegol**. IZERVAY attaches to a specific protein, called complement component 5 (C5).

IZERVAY is used to treat adult patients with an eye condition called **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**. IZERVAY is injected directly into the eye by your doctor.

This disorder affects the macula, the central part of the retina (the light-sensitive layer at the back of the eye) that is responsible for fine, central vision. In patients with GA secondary to AMD, regions of the retina experience cell death ('atrophy'). These areas can grow and result in a dim or blind spot in your vision and can lead to permanent vision loss.

IZERVAY specifically recognises and blocks the activity of the protein complement C5. By attaching to this protein, this medicine prevents cells in the retina called photoreceptors from dying. An improvement in vision or quality of life has not been demonstrated with IZERVAY. IZERVAY is intended to slow down worsening of the disease.

## 2. What should I know before I am given IZERVAY?

### Warnings

**Do not use IZERVAY if you:**

- are allergic to avacincaptad pegol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have an active or suspected infection in or around the eye.
- have pain or redness in your eye (eye inflammation).

**Check with your doctor if you:**

- have any other medical conditions
- 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.

IZERVAY has not been studied in pregnant women. IZERVAY is not recommended for use during pregnancy.

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

It is unknown whether avacincaptad pegol passes into breast milk. A risk to the baby cannot be excluded. Your doctor will help you decide whether to stop treatment with IZERVAY while you are breastfeeding.

## 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.

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

## 4. How will I be given IZERVAY?

IZERVAY is given as an injection into your eye (intravitreal injection) by a doctor experienced in giving eye injections.

Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully, to prevent infection. Your doctor will numb the eye to reduce or prevent pain from the injection. The doctor will check the eye pressure (intraocular pressure) after the injection.

### How much will I be given?

The recommended dose is 2 mg (0.1 ml) avacincaptad pegol.

### When will I be given IZERVAY?

You will be treated with one injection every month for the first 12 months, followed by once monthly or every other month thereafter.

### If you miss a dose of IZERVAY

If you miss a dose, schedule a new appointment with your doctor as soon as possible.

Speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss and your vision may worsen.

### If you are given too much IZERVAY

As IZERVAY is given by your eye doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given IZERVAY, tell your doctor immediately.

#### 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 being given IZERVAY?

### Things you should do

#### Call your doctor straight away if you:

- develop vision loss, distorted vision, blurry vision or changes in vision while using this medicine
- develop signs of a possible eye infection or inflammation, such as increased redness of the eye, eye pain, increased eye discomfort, blurred or decreased vision, an increased number of small particles in your vision, increased sensitivity to light
- develop signs of a possible retinal detachment/tear, such as flashes of light, an increased number of small particles or cobwebs in your vision, worsening of side vision, curtain like shadow over your field of vision

Remind any doctor, dentist or pharmacist you visit that you are receiving IZERVAY.

### Driving or using machines

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

IZERVAY may cause blurred vision in some people. You should not drive or use machinery until your eyesight has recovered.

### Looking after your medicine

The information on how to store IZERVAY is meant for your doctor, who will be storing, handling, and injecting your medicine. You will not be asked to store IZERVAY at home. It will be stored in the fridge (at 2°C to 8°C) by your doctor. Any unused portion of the solution will not be stored for reuse.

### Getting rid of any unwanted medicine

Any unused medicine or waste material will be disposed of by your doctor in accordance with local requirements.

## 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
<b>Eye-related:</b> <ul style="list-style-type: none"><li>• Bleeding from small blood vessels in the outer layer of the eye</li><li>• Eye pain</li><li>• Increase in pressure inside the eye</li><li>• Scratch or damage to the clear layer of the eyeball that covers the iris</li><li>• Inflammation or reddening of eyelids or the surface of the eye</li><li>• Inflammation, bleeding or cells in the gel-like substance inside the eye</li><li>• Feeling of having something in your eye</li><li>• Blurred vision</li><li>• Moving spots or dark shades in your vision (floaters)</li><li>• Flashes of light in your vision</li><li>• Visual impairment</li><li>• Temporary decreased sharpness of vision</li><li>• Temporary loss of vision</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects.</b>

## Serious side effects

Serious side effects	What to do
<b>Eye-related:</b> <ul style="list-style-type: none"><li>• Serious inflammation or infection inside the eye</li><li>• Lack of blood supply to the optic nerve leading to sudden loss of vision</li><li>• Bleeding from small blood vessels in the retina</li><li>• Growth of abnormal blood vessels which leak blood and fluid and can damage the cells at the back of the eye</li><li>• Wet AMD is a serious and vision threatening condition that is associated with IZERVAY. Wet AMD requires urgent eye specialist review and treatment</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>

**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 IZERVAY contains

<b>Active ingredient (main ingredient)</b>	avacincaptad pegol
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium chloride</li><li>• monobasic sodium phosphate monohydrate</li><li>• dibasic sodium phosphate heptahydrate</li><li>• water for injections</li></ul>

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

## What IZERVAY looks like

IZERVAY is a clear to slightly opalescent, colourless to slightly yellowish aqueous solution and comes in a glass vial with rubber stopper, aluminium seal and a white plastic cap.

Pack size of one vial of IZERVAY with one sterile filter needle and one sterile syringe for single use only.

(AUST R 447210)

### Who distributes IZERVAY

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Tel: 1800 751 755 (Medical Information)

Email: [aaumedinfo@astellas.com](mailto:aaumedinfo@astellas.com) (Medical Information)

Website: [www.astellas.com/au](http://www.astellas.com/au)

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