

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 SYFOVRE?

SYFOVRE contains the active ingredient pegcetacoplan. SYFOVRE is injected into your eye to treat the eye disorder called geographic atrophy (GA).

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

2. What should I know before I am given SYFOVRE?

You must not be given SYFOVRE if you have ever had an allergic reaction to pegcetacoplan or any of the ingredients listed at the end of the CMI.

You must not be given SYFOVRE if you have an infection in or around your eye

You must not be given SYFOVRE if you have inflammation in or around your eye.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given SYFOVRE?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, as medicines can affect each other, causing side effects.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is SYFOVRE given?

SYFOVRE will be injected into your eye by your doctor once every two months.

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

5. What should I know while I am being given SYFOVRE?

Things you should do	• Tell your doctor if you experience any problems during your treatment with SYFOVRE. • Remind any doctor and other health professionals including your dentist or pharmacist that you are being treated with SYFOVRE.
Driving or using machines	• You may not see as well after SYFOVRE is injected into your eye and after the associated eye examinations. Do not drive or use machines until your eyesight has returned to normal.
Looking after your medicine	• It is unlikely that you will have to store SYFOVRE at home. If you have to store it, keep it in the refrigerator at 2°C - 8°C in the outer carton.

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

6. Are there any side effects?

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.

SYFOVRE[®] (sy-fo-vree)

Active ingredient(s): Pegcetacoplan (*peg-set-a-koé-plan*)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYFOVRE. 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 SYFOVRE.

Where to find information in this leaflet:

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

1. Why am I being given SYFOVRE?

SYFOVRE contains the active ingredient pegcetacoplan.

Pegcetacoplan belongs to a group of medicines called ophthalmologicals. It has been designed to attach to the C3 complement protein, which is a part of the body's defence system called the 'complement system'.

SYFOVRE is injected into the eye by your doctor to treat an eye disorder called geographic atrophy (GA).

GA is the dry, advanced form of age-related macular degeneration (AMD) that can lead to permanent vision loss that cannot be corrected with eye glasses or surgery.

GA affects the retina, the part of the eye which senses light and sends signals to the brain so you can see. The retina contains photoreceptors which are light sensitive cells that are responsible for converting light into signals that are sent to the brain. In people with GA, these cells die within the central part of the retina, which is called the macula. This results in patches of damaged macula (lesions), causing dim or dark spots in the field of vision. As the cells around the patches continue to die and the lesions grow, loss of vision can get worse and can lead to blindness.

How SYFOVRE works

GA can progress when the immune system in your eye is overactivated and damages your retina. SYFOVRE helps control the overactivation of the immune system in your eye. GA cannot be cured, but treatment with SYFOVRE slows down the damage to the retina.

If you have any questions about SYFOVRE, how it works or why this medicine has been prescribed for you, ask your doctor.

2. What should I know before I am given SYFOVRE?

Your doctor should discuss the risks and benefits of SYFOVRE injections into the eye for GA prior to starting treatment.

Warnings

You must not be given SYFOVRE if:

- You are allergic to pegcetacoplan or any of the ingredients listed at the end of this leaflet.

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

- You have or suspect you have an infection in, or around, your eye
- You have inflammation in, or around, your eye (may be indicated by pain and/or redness).

Check with your doctor if you:

- Have any other medical conditions
- Take any medicines for any other conditions
- Have a history of seeing flashes of light or floaters (small specks in your vision) and/or if you have noticed an increase in the number or size of floaters since your last injection
- Have glaucoma (an eye condition usually caused by high pressure in the eye).

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.

Women who could become pregnant must use an effective method of birth control during treatment with SYFOVRE. **If you become pregnant or think you are pregnant during treatment, tell your doctor right away.**

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breast-feeding is not recommended during treatment with SYFOVRE because it is not known whether SYFOVRE passes into human milk.

Use in children and adolescents

SYFOVRE is not used in children and adolescents, because GA occurs only in adults.

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 SYFOVRE.

4. How is SYFOVRE given?

How much and how often SYFOVRE is given

The recommended dose is 15 mg of SYFOVRE, given as a single injection into your affected eye(s) once every two months.

How you will be given SYFOVRE

SYFOVRE is given as an injection into your eye (intravitreal injection) under clean and sterile conditions by a doctor experienced in giving eye injections.

Before the injection, your doctor will clean your eye carefully, to prevent infection. You will also be given an anaesthetic eye drop to numb the eye and to reduce or prevent pain from the injection.

After the injection, your doctor will test your vision, and may check your eye pressure.

How long will you be given SYFOVRE

GA is a disease that cannot be cured and therefore needs long-term treatment. If you have questions about how long you will receive SYFOVRE, ask your doctor.

If you miss a dose of SYFOVRE

If you miss a dose of SYFOVRE, schedule a new appointment with your doctor as soon as possible. Do not wait until the next planned dose.

Before stopping treatment with SYFOVRE

Always speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss.

If you are given too much SYFOVRE

Your doctor will ensure you are given the correct amount of SYFOVRE. If you think that you have been given too much SYFOVRE, 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 I am being given SYFOVRE?

Things you should do

If you experience any problems during the treatment, tell your doctor.

Call your doctor straight away if you:

- have sudden loss or disturbance of vision
- develop redness of the eye, eye pain, increased discomfort, worsening eye redness, an increased number of small specks (floaters) in your vision or an increased sensitivity to light.

Remind any doctor and other health professionals including your dentist or pharmacist that you are being treated with SYFOVRE.

Things you should not do

Do not stop treatment with SYFOVRE unless your doctor tells you to. Stopping treatment may increase your risk of vision loss.

It is important for you to know that:

- injections with SYFOVRE may cause an increase in eye pressure (intraocular pressure) in some patients within minutes of the injection. Your doctor or nurse will check your eye pressure if needed after each injection (see section 4 How is SYFOVRE given).

Driving or using machines

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

After your injection or eye examinations associated with SYFOVRE treatment, your eyesight may be temporarily impaired. If this occurs, do not drive or use machines until these effects have passed.

Looking after your medicine

It is unlikely that you will have to store SYFOVRE at home. If you have to store it:

- Store SYFOVRE in the refrigerator at 2°C - 8°C
- Keep the vial inside the carton to protect from light.

Keep SYFOVRE where young children cannot reach it.

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
• eye discomfort including eye pain, eye irritation, or abnormal sensation in the eye • moving small spots (floaters) in your line of vision • bleeding from small blood vessels in the outer layer of the eye • detachment of the gel-like substance inside the eye • damage to the clear layer of the eyeball that covers the iris • formation of a layer of scar tissue behind a lens implant causing cloudy vision • increase in eye pressure.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reactions, inflammation and infections are serious side effects. Signs of these include: • neovascular (wet) age-related macular degeneration • eye pain • increased discomfort • worsening eye redness • blurred or decreased vision, an increase in the number of floaters (small specks in your vision) • increased sensitivity to light • a sudden decrease or change in vision. Other serious side effects may include: • torn retina in the eye • bleeding in the retina • a severe form of inflammation of the blood vessels in the back of the eye called retinal vasculitis. Wet AMD is a serious and vision-threatening condition that is associated with SYFOVRE in up to 7% of patients. Wet AMD requires urgent eye specialist review and treatment. Other serious side effects occurred in less than 1% of patients in clinical trials.	Call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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. 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 SYFOVRE contains

Active ingredient (main ingredient)	Pegcetacoplan
Other ingredients (inactive ingredients)	Trehalose dihydrate Glacial acetic acid Sodium hydroxide Sodium acetate trihydrate Water for injections

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

What SYFOVRE looks like

SYFOVRE is a clear, colourless to slightly yellowish aqueous solution contained in a 2 mL glass vial. (Aust R 404733).

SYFOVRE comes in cartons of 1 vial.

Who distributes SYFOVRE

Apellis Australia Pty Ltd
Level 3, 141 Camberwell Road
Hawthorn East, VIC, 3123
Australia
Ph: 1800 879 456

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