

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 being given Afqlir?

Afqlir contains the active ingredient aflibercept. Afqlir is given to treat adults for neovascular wet age-related macular degeneration (also known as wet AMD), visual impairment due to macular oedema after central retinal vein occlusion (also known as CRVO), visual impairment due to macular oedema after branch retinal vein occlusion (also known as BRVO), diabetic macular oedema (DME), and visual impairment due to myopic choroidal neovascularisation (also known as myopic CNV).

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Afqlir 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 is Afqlir given?

Afqlir is given by an ophthalmologist (eye doctor) as an injection into your eye usually under a local anaesthetic. In adult patients, the usual dose of Afqlir is 0.05 mL or 50 microlitres.

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

5. What should I know while being given Afqlir?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Afqlir.• Tell your doctor if you experience signs of infection, inflammation or you become pregnant.
Driving or using machines	<ul style="list-style-type: none">• You may experience temporary disturbances to your vision after an injection with Afqlir.• Do not drive or use machinery after your Afqlir injection as you may experience some temporary problems with vision.
Drinking alcohol	<ul style="list-style-type: none">• There are no known interactions between Afqlir and alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Your ophthalmologist (eye doctor) will treat you with Afqlir.• It is unlikely you will have to store Afqlir at home.

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Afqlir.

Common side effects: bloodshot eye (conjunctival haemorrhage), eye pain, clouding of the lens (cataract), increased eye pressure, vitreous detachment, moving spots in vision. Serious side effects: bleeding in the eye, pus in the eye, inflammation in the eye, damage to the front layer of the eyeball, clouding of the lens, decreased sharpness of vision, stroke and heart attack.

For the full list of side effects and 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.

AFQLIR[®] (af•kleer)

Active ingredient(s): *aflibercept*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Afqlir?

Afqlir contains the active ingredient aflibercept. Afqlir is a type of treatment known as anti-vascular endothelial growth factor (anti-VEGF).

Afqlir is used to treat adults for the following eye conditions:

- neovascular wet age-related macular degeneration (also known as wet AMD)
- visual impairment due to macular oedema after central retinal vein occlusion (also known as CRVO)
- visual impairment due to macular oedema after branch retinal vein occlusion (also known as BRVO)
- diabetic macular oedema (DME)
- visual impairment due to myopic choroidal neovascularisation (also known as myopic CNV).

Wet AMD is a condition in which abnormal blood vessels grow in the back of the eye (retina). These blood vessels can leak blood and fluid into the retina and damage it leading to vision loss.

CRVO is caused by a blockage in the main blood vessel that transports blood away from the retina, in the back of your eye. The blockage stops blood from flowing in and out of the retina which causes swelling (macular oedema) and can damage your eyesight.

DME is a swelling of the retina occurring in patients with diabetes due to leakage of fluid from blood vessels within the retina.

BRVO is caused by a blockage in one or more branches of the main blood vessel that transports blood away from the retina, in the back of your eye. The blockage stops blood from flowing in and out of the retina which causes swelling (macular oedema) and can damage your eyesight.

Myopic CNV is a severe form of myopia (short sightedness) which leads to extremely elongated eyes with additional

defects in some layers in the back of the eye. This triggers the abnormal formation of new blood vessels which can cause bleeding and eventually may lead to loss of vision.

Proteins called vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) play an important part in the development of new blood vessels in your eye which contributes to the progression of wet AMD or myopic CNV and the development of swelling (macular oedema) due to either CRVO, BRVO or DME.

Aflibercept, the active substance in Afqlir specifically binds to VEGF-A and PlGF proteins and blocks the activity of these groups of factors. By blocking these proteins, Afqlir can stop the growth and leakage of abnormal blood vessels and swelling of the retina in the eye, which in turn can help improve your eyesight or stop it from getting worse.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Warnings

You must not be given Afqlir if:

- you are allergic to aflibercept, 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 an infection in or around your eye.
- you have or suspect severe inflammation of the eye (pain or redness).

If you experience an allergic reaction, tell your doctor or get emergency medical help right away. Some of the symptoms of an allergic reaction may include:

- itching of the skin, with a red rash, or raised bumps
- swelling of the throat, tongue, face, lips or other parts of the body
- difficulty in breathing or swallowing
- dizziness

If you are not sure whether you should be given this medicine, talk to your doctor.

Do not give this medicine to children under the age of 18 years. There is not enough information to recommend the use of Afqlir for children or adolescents.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- think you may be allergic to aflibercept or any of the ingredients in Afqlir
- had any prior issues or problems with injections into your eyes

- have glaucoma (injection with Afqilir may trigger an increase in eye pressure in some patients within sixty minutes of the injection and your doctor may monitor this after each injection)
- have ever had a stroke or experienced transient signs of a stroke (known as a “TIA” or “mini-stroke”)
- have previously had or are planning to have an eye surgery within the past or next four weeks.

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.

It is recommended that you use effective contraception during Afqilir treatment and for at least three months after the last injection of Afqilir.

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

Afqilir is not recommended during breastfeeding as it is not known whether it passes into breast milk.

If you have not told your doctor about any of the above, tell him/her before you are given Afqilir.

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 Afqilir.

4. How is Afqilir given?

Afqilir is given by your ophthalmologist (eye doctor) as an injection into your eye usually under a local anaesthetic.

Afqilir is given as a single injection into your eye.

How much is given

The recommended dose of Afqilir is 50 microlitres (equivalent to 2 mg aflibercept). This is the only dose of Afqilir available.

The interval between two doses should not be shorter than one month.

If you are being treated for wet AMD:

- The injection is given once a month for the first three months. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor may decide to adjust the treatment interval for your next injection.

If you are being treated for impaired vision due to macular oedema caused by CRVO or BRVO:

- You will start your treatment with monthly injections. After the first three injections, your doctor will determine the most appropriate treatment schedule for you based on your vision and test results at each visit.
- If considered appropriate, your doctor may decide to gradually increase or adjust the treatment interval for your next injection.

If you are being treated for DME:

- The injection is given once a month for the first five months. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor may decide to adjust the treatment interval for your next injection.

If you are being treated for myopic CNV:

- You will start your treatment with one injection and you will receive additional injections only if, during subsequent examinations, your doctor finds that your disease persists.

If you forget a treatment

Your doctor will give you Afqilir so it is unlikely that you will forget a treatment.

If you miss a treatment with Afqilir, you need to contact your doctor to make a new appointment as soon as possible.

If you stop treatment with Afqilir, your disease may get worse.

If you are given too much Afqilir

If you are given more Afqilir than you need, your doctor will check the pressure in your eye and treat it if it is increased. If you feel unwell after receiving Afqilir contact your doctor.

5. What should I know while being given Afqilir?

Things you should do

Tell your doctor straight away if you:

- **experience any problems during the treatment, especially if you are being given Afqilir injections into both of your eyes at the same time.**
You may be more likely to experience side effects if you receive an injection to both of your eyes at the same time.
- **develop any signs of inflammation and/or infection of the eye such as redness of the eye, eye pain, light sensitivity and/or vision changes, seeing flashes of light with moving spots or floaters, progressing to a loss of sight or blurred vision.**
It is important to have any symptoms diagnosed and treated as soon as possible. A serious eye infection or eye disorder can sometimes develop after an injection into the eye. See Section [6. Are there any side effects?](#) for information on other serious side effects.

If you are treated for visual impairment due to macular oedema in diabetes tell your doctor if you think that the effect of the treatment is being lost.

If you become pregnant while being treated with this medicine, tell your doctor immediately.

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

Things you should not do

Driving or using machines

You may experience temporary disturbances to your vision after each eye injection and examination. **Do not drive or use machinery until your vision has recovered completely. Be careful before you drive or use any machinery or tools until you know how AfqIir affects you.**

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with AfqIir.

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
Eyes: <ul style="list-style-type: none"> Bloodshot eye (conjunctival hemorrhage) Moving spots in vision (vitreous floaters) Eye irritation or discomfort Sensation of having something in the eye 	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: <ul style="list-style-type: none"> Difficulty in breathing or swallowing Swelling of the throat, tongue, face, lips or other parts of the body Itching of the skin, with a red rash or raised bumps Dizziness Eyes: <ul style="list-style-type: none"> Bleeding in the eye Pain at the injection site Swelling or irritated eyelid 	Go straight to the Emergency department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> Redness of the eye Detachment of the gel-like substance inside the eye from the retina (vitreous detachment) Pus in the eye Inflammation in the eye Eye pain Increase in eye pressure (intraocular pressure) Decreased sharpness of vision Damage to the front layer of the eyeball (corneal abrasion, corneal erosion) Blurred vision Certain forms of clouding of the lens (cataract) Flashes of light and floaters (retinal detachment) 	
Stroke and heart attack: <ul style="list-style-type: none"> Signs of stroke, such as weakness or numbness of limbs, drooping of the face, trouble standing or walking, or difficulty speaking or swallowing Signs of heart attack, such as chest pain which may spread to the neck and shoulders 	

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.

Some of these side effects (for example, an increase in the pressure inside your eye) can only be found when your doctor does tests to check your progress.

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 for Australia or to Centre for Adverse Reactions Monitoring at <https://pophealth.my.site.com/carmreportnz/s/> for New Zealand. 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 Afqlir contains

Active ingredient (main ingredient)	40 mg/mL aflibercept
Other ingredients (inactive ingredients)	histidine histidine hydrochloride monohydrate trehalose dihydrate polysorbate 20 hydrochloric acid water for injections

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

What Afqlir looks like

Afqlir is a clear, colourless to slightly brownish-yellow solution, supplied as a single dose in a glass vial or pre-filled syringe for the treatment of one eye.

Pre-filled syringe

Each carton includes a sealed blister pack with a pre-filled syringe containing approximately 165 microlitres of solution. (Aust R 445959)

Vial

Each carton includes a vial containing approximately 240 microlitres of solution and a filter needle for withdrawal of the vial contents. (Aust R 445960)

Not all presentations may be marketed.

Who distributes Afqlir

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