EYLEA® (eye•leah)

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 EYLEA®?

EYLEA contains the active ingredient aflibercept (rch).

EYLEA® 2 mg is used to treat adults in:	1) neovascular (wet) age-related macular degeneration (wet AMD), 2) diabetic macular oedema (DME), 3) visual impairment due to macular oedema after central retinal vein occlusion (also known as CRVO), 4) visual impairment due to macular oedema after branch retinal vein occlusion (also known as BRVO), and 5) visual impairment due to myopic choroidal neovascularisation (myopic CNV).
EYLEA® 8 mg is used to treat adults in:	1) neovascular (wet) age-related macular degeneration (wet AMD) and, 2) diabetic macular oedema (DME).

For more information, see Section 1. Why am I using EYLEA®? in the full CMI.

2. What should I know before I use EYLEA®?

Do not use 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 use EYLEA®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EYLEA® 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 use EYLEA®?

EYLEA® 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 EYLEA® 2 mg is 0.05 mL or 50 microlitres; and for EYLEA® 8 mg is 0.07 mL or 70 microlitres. More instructions can be found in Section 4. How do I use EYLEA®? in the full CMI.

5. What should I know while using EYLEA®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using EYLEA®. • Tell your doctor if you experience signs of infection, inflammation or you become pregnant.
Driving or using machines	• Patients may experience temporary visual disturbances after an intravitreal injection with Eylea®. **Do not** drive or use machinery after your injection as you may experience some temporary problems with vision.
Drinking alcohol	• There are no known interactions between EYLEA® and alcohol.
Looking after your medicine	• Your ophthalmologist (eye doctor) will treat you with EYLEA®. There is no need to store this medicine at home.

For more information, see Section 5. What should I know while using EYLEA®? in the full CMI.

6. Are there any side effects?

Common side effects: bloodshot eye (conjunctival haemorrhage), eye pain, clouding of the lens (cataract), intraocular 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. 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.

Note: Eylea 40 mg/mL is also referred to as Eylea 2 mg
Eylea 114.3 mg/mL is also referred to as Eylea 8 mg

EYLEA® (eye•leah)

Active ingredient(s): Aflibercept (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using EYLEA®. **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 EYLEA®.**

Where to find information in this leaflet:

1. Why am I using EYLEA®?
2. What should I know before I use EYLEA®?
3. What if I am taking other medicines?
4. How do I use EYLEA®?
5. What should I know while using EYLEA®?
6. Are there any side effects?
7. Product details

1. Why am I using EYLEA®?

EYLEA® 2 mg is used to treat adults for the following eye conditions:

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

EYLEA® 8 mg is used to treat adults for the following eye conditions:

- **neovascular (wet) age-related macular degeneration (wet AMD)**
- **diabetic macular oedema (DME)**

EYLEA® contains the active ingredient Aflibercept. Aflibercept, the active substance in EYLEA®, specifically binds to Vascular Endothelial Growth Factor A (VEGF-A) and Placental Growth Factor (PlGF) and blocks the activity of these group of factors, present in the 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. By blocking these proteins, EYLEA® 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 if from getting worse. EYLEA® can help to stabilise, and in many cases, improve the vision loss related to wet AMD, DME, CRVO, BRVO and mCNV.

EYLEA® 2 mg and EYLEA® 8 mg are used in patients with neovascular (wet) age-related macular degeneration (wet AMD), which 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.

EYLEA® 2 mg and EYLEA® 8 mg are used to treat diabetic macular oedema (DME) which is a swelling of the retina occurring in patients with diabetes due to leaking of fluid from blood vessels within the macula.

EYLEA® 2 mg is used to treat CRVO which 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.

EYLEA® 2 mg is used to treat BRVO which 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.

EYLEA® 2 mg is used to treat Myopic CNV which 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.

2. What should I know before I use EYLEA®?

Warnings

Do not use EYLEA® 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 use this medicine.

You must not be given this medicine if you have or suspect:

- an infection in or around the eye
- severe inflammation of the eye (pain or redness)

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 EYLEA for children or adolescents.

Check with your doctor if you:

- Had any prior issues or problems with injections into your eyes.

- Have glaucoma (injection with EYLEA® may trigger an increase in eye pressure in some patients within 60 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.

Eylea 2 mg: It is recommended that you use effective contraception during treatment and for at least 3 months after the last injection of EYLEA®.

Eylea 8 mg: It is recommended that you use effective contraception during treatment and for at least 4 months after the last injection of EYLEA®.

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

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

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 EYLEA®.

4. How will I be given EYLEA®?

How much to use

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

How EYLEA® is given

EYLEA® is given as a single injection into your eye.

How much EYLEA® is given

EYLEA® 2 mg:

The recommended dose of EYLEA® 2 mg is 50 microlitres (equivalent to 2 mg aflibercept).

The time between two doses injected into the same eye should not be shorter than one month.

If you are being treated for wet AMD with EYLEA® 2 mg: The injection is given once a month for the first 3 months followed by one injection every 2 months. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor may decide to gradually increase or adjust the treatment interval for your next injection.

If you are being treated for DME with EYLEA® 2 mg: The injection is given once a month for the first 5 months followed by one injection every 2 months. Treatment interval may be kept at every 2 months or adjusted to your condition, based on your doctor's examination. Your doctor will decide on the schedule for follow up examinations.

If you are being treated for impaired vision due to macular oedema caused by CRVO or BRVO with EYLEA® 2 mg: You will start your treatment with monthly injections. After the first 3 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 myopic CNV with EYLEA® 2 mg: 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.

EYLEA® 8 mg:
The recommended dose of EYLEA® 8 mg is 70 microlitres (equivalent to 8 mg aflibercept).

The time between 2 doses injected into the same eye should not be shorter than one month.

If you are being treated for wet AMD or for DME with EYLEA® 8 mg: The treatment is started with one injection of EYLEA® 8 mg per month for the first 3 months. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor will decide whether and when you need to receive the next injections of EYLEA® 8 mg.

If you forget to use EYLEA®

Your doctor will give you EYLEA® so it is unlikely that you will forget to use this medicine.

If you miss a EYLEA® treatment, you need to contact your doctor to arrange another appointment as soon as possible.

If you stop EYLEA® treatment, your disease may get worse.

If you use too much EYLEA®

If you are given more EYLEA® than you need, your doctor will check the pressure in your eye and treat it if is increased. This is unlikely as your doctor will only give you the recommended dose, they will not give you too much EYLEA®. If you feel unwell after receiving EYLEA® contact your doctor.

5. What should I know while using EYLEA®?

Things you should do

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

Call your doctor straight away if you:

Tell your doctor immediately if you develop 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.

A serious eye infection or eye disorder can sometimes develop after an injection into the eye.

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 EYLEA®.

Things you should not do

Driving or using machines

Patients may experience temporary visual disturbances after an intravitreal injection and the associated eye examinations. Patients should not drive or use machinery until visual function has recovered sufficiently. Be careful before you drive or use any machines or tools until you know how EYLEA® affects you.

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 disorders: • Bloodshot eye (conjunctival haemorrhage) • 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
Eye disorders • Bleeding in the eye • Pain at the injection site • Swelling or irritated eyelid • 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, lenticular opacities) • Flashes of light and floaters (retinal detachment) **Immune system disorders:** • Hypersensitivity (rash, itching or hives caused by an allergic reaction) **Blood clot related disorders:** • signs of a stroke, such as weakness or numbness of limbs or face, difficulty speaking or swallowing. • signs of heart attack, such as chest pain which may spread to the neck and shoulders	**Go straight 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. Some side effects (e.g. an increased intraocular

pressure in the 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 the 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.

7. Product details

This medicine is only available with a doctor's prescription.

What EYLEA® 2 mg contains

Active ingredient (main ingredient)	Aflibercept (rch)
Other ingredients (inactive ingredients)	Polysorbate 20 Monobasic sodium phosphate monohydrate Dibasic sodium phosphate heptahydrate Sodium chloride Sucrose Water for injections

What EYLEA® 8 mg contains

Active ingredient (main ingredient)	Aflibercept (rch)
Other ingredients (inactive ingredients)	Polysorbate 20 Arginine hydrochloride Histidine Histidine hydrochloride monohydrate Sucrose Water for injections

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

What EYLEA® 2 mg looks like

EYLEA® 2 mg is supplied in a clear, colourless, single-use glass vial. The vial contains approximately 100 µL of extractable volume of a sterile, clear, colourless to pale yellow solution.

Vial: Aust R 180859 (concentration 40 mg/mL).

EYLEA® 2 mg is supplied in a sterile sealed blister pack with a pre-filled syringe. The pre-filled syringe contains approximately 90 µL of extractable volume of a sterile, clear, colourless to pale yellow solution.

Pre-filled syringe: Aust R 180860 (concentration 40 mg/mL).

What EYLEA® 8 mg looks like

EYLEA® 8 mg is supplied in a clear, colourless, single-use glass vial. The vial contains approximately 100 µL of extractable volume of a sterile, clear to slightly opalescent, colourless to pale yellow solution.

Vial: Aust R 405862 (concentration 114.3 mg/mL).

EYLEA® 8 mg is supplied in a sterile sealed blister pack with a pre-filled syringe. The pre-filled syringe contains approximately 100 µL of extractable volume of a sterile, clear to slightly opalescent, colourless to pale yellow solution.

Pre-filled syringe: Aust R 454465 (concentration 114.3 mg/mL).

Not all presentations or strengths may be marketed in Australia and New Zealand.

Who distributes EYLEA®

Bayer Australia Ltd

ABN 22 000 138 714

875 Pacific Highway

Pymble NSW 2073

Website: www.bayer.com.au

Bayer New Zealand Ltd

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Shortland Street

Auckland 1140

New Zealand

Website: www.bayer.co.nz

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See TGA website (www.ebs.tga.gov.au) in Australia or Medsafe website (www.medsafe.govt.nz) in New Zealand for latest Consumer Medicine Information.

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