

Your guide to Eylea®



Table of contents:

● Your Guide to Eylea	4
● Information for patients prescribed Eylea for the treatment of wet Age-related Macular Degeneration (wAMD).....	5
● Information for patients prescribed Eylea for the treatment of Diabetic Macular Edema (DME)	6
● Information for patients prescribed Eylea for the treatment of macular edema secondary to Central Retinal Vein Occlusion (CRVO)	7
● Information for patients Prescribed Eylea for the treatment of macular edema secondary to Branch Retinal Vein Occlusion (BRVO)	8
● Information for patients prescribed Eylea for the treatment of myopic Choroidal Neovascularization (mCNV).....	9
● Information for patients in all indications	
- What is Eylea?	10
- Who is Eylea for?	11
- What should your doctor know before you are treated with Eylea?	12
- How can I get ready for my Eylea appointment?	13
- What can I expect after the Eylea treatment?	13
- Does Eylea have side effects?.....	14
- Reporting about side effects	15
- What if I have concerns or questions?.....	15

Your guide to Eylea®

Your doctor has prescribed Eylea because you have been diagnosed with one of the conditions listed in the table below:

Indication	Eylea Dose
Wet Age-Related Macular Degeneration (wAMD)	Eylea 2 mg and Eylea 8 mg
Visual impairment due to Diabetic Macular Edema (DME)	
Visual impairment due to macular edema secondary to Central Retinal Vein Occlusion (CRVO)	Eylea 2 mg
Visual impairment due to macular edema secondary to Branch Retinal Vein Occlusion (BRVO)	
Visual impairment due to myopic Choroidal Neovascularization (mCNV)	

For more information on all indications please refer to the patient Information Leaflet (PIL) available in the product package. Read the PIL before you start using Eylea. The PIL is also available on the Israeli Drug Registry via the following link: <https://israel drugs.health.gov.il/#!/byDrug>

The booklet is available as a digital version and comes with an audio guide. The audio guide is a readout of the text in this patient booklet.

A digital version of this booklet, is available on the Ministry of Health website in the following link:

https://www.gov.il/he/Departments/DynamicCollectors/patient-safety-information?skip=0&safety_information_lang=1&safety_information_audience=1

For the audio guide, please scan the QR code:



Information for patients prescribed Eylea for the treatment of wet Age-Related Macular Degeneration (wAMD)

Your doctor has prescribed you Eylea (aflibercept solution for injection) for the treatment of wAMD. The Eylea 2 mg dose and the Eylea 8 mg dose have been studied in wAMD. Your doctor may give you either the Eylea 2 mg dose or the Eylea 8 mg dose, depending on your situation.

What is wAMD?

The retina is the layer of cells lining the back wall inside your eye. It senses light and sends messages to the brain, enabling you to see. The macula is an important area at the center of the retina that allows you to clearly see details of objects in front of you, like faces and words in books. wAMD occurs when new, abnormal blood vessels grow under the retina. This can occur with age and the accumulation of degradation products in the retina. The growth of these abnormal vessels is due to higher than normal levels in the eye of a protein called VEGF. VEGF is an abbreviation for vascular endothelial growth factor, and it is involved in making the abnormal blood vessels in the eye. These vessels may leak blood or other fluids and may cause scarring of the macula. Over time, this can lead to permanent central vision loss.




Information for patients prescribed Eylea for the treatment of Diabetic Macular Edema (DME)

Your doctor has prescribed you Eylea (afibercept solution for injection) for the treatment of DME. The Eylea 2 mg dose and the Eylea 8 mg dose have been studied in DME. For the treatment of DME, your doctor may give you either the Eylea 2 mg dose or the Eylea 8 mg dose, depending on your situation.


What is DME?

Diabetic Macular Edema is a condition that occurs when fluid builds up in the retina. The retina is the layer of cells lining the back wall inside your eye. It senses light and sends messages to the brain, enabling you to see. The macula is an important area at the center of the retina that allows you to clearly see details of objects in front of you, like faces and words in books. Diabetes goes along with high blood sugar values or high fluctuation of blood sugar. This can result in damage of small blood vessels and reduced blood circulation in the eye, and leads to swelling in the retina and blurry vision. The swelling is due to higher than normal levels in the eye of a protein called VEGF. VEGF is an abbreviation for vascular endothelial growth factor, and it creates leaky blood vessels that results in the swelling. Over time, the swelling can damage the retina, and can lead to permanent central vision loss.






Information for patients prescribed Eylea for the treatment of macular edema secondary to Central Retinal Vein Occlusion (CRVO)




Your doctor has prescribed you Eylea 2 mg dose (aflibercept solution for injection) for the treatment of CRVO. The Eylea 8 mg dose has not been studied in CRVO.

What is CRVO?

The retina is the layer of cells lining the back wall inside your eye. It senses light and sends messages to the brain, enabling you to see. The macula is an important area at the center of the retina that allows you to clearly see details of objects in front of you, like faces and words in books. The retina has one main artery and one main vein. With age, the elasticity of blood vessels changes and they can become clogged or congested more easily. CRVO occurs when the main retina vein becomes blocked. This is like a thrombosis in the retina, and it results in a backlog of blood in the vessel. This causes the retina to release VEGF. VEGF is an abbreviation for vascular endothelial growth factor, and it is involved in making the blood vessels grow, but can make them leaky. These leaky blood vessels cause swelling and unwanted blood in the eye, which can damage the retina. At the same time, the original blockage may still exist causing the problem to worsen. As a result, your central vision can be severely affected.






Information for patients prescribed Eylea for the treatment of macular edema secondary to Branch Retinal Vein Occlusion (BRVO)

Your doctor has prescribed you Eylea 2 mg dose (aflibercept solution for injection) for the treatment of BRVO. The Eylea 8 mg dose has not been studied in BRVO.

What is BRVO?

The retina is the layer of cells lining the back wall inside your eye. It senses light and sends messages to the brain, enabling you to see. The macula is an important area at the center of the retina that allows you to clearly see details of objects in front of you, like faces and words in books. With age, the elasticity of blood vessels changes and they can become clogged or congested more easily. BRVO occurs when one or more branches of the main retina vein become blocked. This is like a thrombosis in one part of the retina. It results in a backlog of blood in the vessel. This causes the vessel to release VEGF. VEGF is an abbreviation for vascular endothelial growth factor, and it is involved in making the blood vessels leaky as well as in the formation of new blood vessels. These leaky blood vessels cause swelling and unwanted blood in the eye. The swelling can include the macula, and if it does, your central vision can be severely affected. Over time, if there is no blood circulation in this area, nerve cells in the eye can die and your vision can become worse.





Information for patients prescribed Eylea for the treatment of myopic Choroidal Neovascularization (mCNV)



Your doctor has prescribed you Eylea 2 mg dose (aflibercept solution for injection) for the treatment of mCNV. The Eylea 8 mg dose has not been studied in mCNV.

What is mCNV?

The retina is the layer of cells lining the back wall inside your eye. It senses light and sends messages to the brain, enabling you to see. In people with high myopia (short-sightedness), enlargement or elongation of the eyeball occurs. This can lead to stretching and thinning of the retina. This thinning can cause new blood vessel growth from the choroid. The choroid is a layer of the eye behind the retina, which provides blood supply to the eye. The growth of these new and leaky vessels is due to higher than normal levels in the eye of a protein called VEGF. VEGF is an abbreviation for vascular endothelial growth factor. These new blood vessels can cause leakage of blood and fluid into the eye, which leads to blurred or distorted central vision.

Information for patients in all Indications:

What is Eylea?

Eylea is a type of treatment known as an anti VEGF. Anti VEGF is an abbreviation for anti-vascular endothelial growth factor, and this is a description of how Eylea works to protect your vision. Eylea blocks VEGF, and this action helps reduce the fluid in the retina and can lead to vision improvement and maintenance.

Eylea is a solution (a liquid) that is injected into the eye.

For the indications wAMD and DME - Eylea is available in a 2 mg dose and an 8 mg dose. In these indications your doctor will determine which dose is best suited to meet your individual situation.

For the indications CRVO, BRVO and mCNV – Eylea is available in a 2 mg dose only. Eylea 8 mg has not been studied in these indications.

Your doctor will also recommend a treatment schedule for you and it is very important that you follow it.

Who is Eylea for?

Eylea is for people who have been diagnosed with one of the following conditions:

Indication	EYLEA Dose
wet Age-related Macular Degeneration (wAMD)	Eylea 2 mg and Eylea 8 mg
Diabetic Macular Edema (DME)	
Central Retinal Vein Occlusion (CRVO)	Eylea 2 mg
Branch Retinal Vein Occlusion (BRVO)	
myopic Choroidal Neovascularization (mCNV)	

Eylea 8 mg was not studied in CRVO, BRVO and mCNV.

For more information on all indications please refer to the patient Information Leaflet (PIL) inside the product package. The PIL is also available on the Israeli Drug Registry in the following link: <https://israel drugs.health.gov.il/#!/byDrug>

Do not use Eylea if:

- You are sensitive (allergic) to the active ingredient (aflibercept) or to any of the other ingredients in this medicine. See section 6 of the patient Information Leaflet.
- You have active or suspected infection in or around the eye.
- You have severe inflammation of the eye (indicated by pain or redness).

What should your doctor know before you are treated with Eylea?

Before your Eylea treatment starts, make sure to tell your doctor and other health care providers if you:

- Have an infection in or around your eye
- If you currently have redness in your eye or if there is any pain in your eye
- Think you may be allergic to iodine, any pain killers or any of the ingredients in Eylea
- Have had any issues or problems with eye injections before
- Have glaucoma or a history of high pressure in your eye
- If you see, or have seen, flashes of light or 'floaters' in your vision
- Are taking any medications, with or without a prescription
- Had or will have eye surgery within 4 weeks before or after Eylea treatment
- Are pregnant, planning to become pregnant or breastfeeding. There is no information about the safety of using Eylea in pregnant women. Eylea 2 mg and Eylea 8 mg should not be used during pregnancy, unless the potential benefit outweighs the potential risk to the fetus. Discuss this with your doctor before treatment with Eylea. Women of childbearing potential should use effective contraception during their treatment with Eylea. If you are treated with the Eylea 2 mg dose, you should continue to use effective contraception for at least three months after the last injection. If you are treated with the Eylea 8 mg dose, you should continue to use effective contraception for at least four months after the last injection. According to very limited information in humans, small amounts of Eylea may enter into the breastmilk. The effects of aflibercept on a breast-fed newborn/infant is unknown. Use of Eylea is not recommended during breastfeeding.

- Have a severe form of CRVO or BRVO (ischemic CRVO or BRVO), treatment with Eylea is not recommended (Eylea 8 mg in not indicated for patients with CRVO or BRVO).

How can I get ready for my Eylea appointment?

After your treatment, your vision may be blurry so you should not drive home. Plan to have a friend or family member take you to your appointment or arrange another way to get there and home again. On the day of your appointment, do not wear any makeup.

What can I expect after the Eylea treatment?

Your doctor may give you some eye tests after your Eylea injection. This may include a test that measures the pressure inside your eye. After your injection, your vision will be blurry so you should not plan to drive until after your vision returns to normal.

During the next few days you may get a bloodshot eye or see moving spots in your vision. These should clear within a few days and if they don't, or if they get worse, you should contact your doctor.

Some people might feel a little bit of pain or discomfort in their eye after their injection. If this does not go away or gets worse, you should contact your doctor.

Does Eylea have side effects?

Just like any medicine, Eylea has the potential to cause side effects. Not everyone who is given an Eylea injection will experience a side effect. Eylea has the same potential side effects whether given as a 2 mg dose or as an 8 mg dose.

Contact your doctor immediately if you have any signs or symptoms listed in the table below as these could be signs of a serious complication with the treatment:

Condition	Some Potential Signs or Symptoms
Infection or inflammation inside the eye	<ul style="list-style-type: none">• Eye pain or increased discomfort• Worsening eye redness• Sensitivity to light• Swelling of the eyelid• Vision changes such as sudden decrease in vision or blurring of vision.
Clouding of the lens (cataract)	<ul style="list-style-type: none">• Blurry vision• Seeing shadows• Less vivid lines and shapes• Color vision changes (e.g. colors looked 'washed out')
Increase in pressure in the eye	<ul style="list-style-type: none">• Seeing halos around lights• Eye pain• Experiencing a red eye• Nausea or vomiting• Vision changes

Condition	Some Potential Signs or Symptoms
A detachment or tear of a layer of the retina	<ul style="list-style-type: none"> • Sudden flashes of light • A sudden appearance or an increase of floaters • A curtain like effect over a portion of the visual area • Vision changes.

For a full list of side effects, please refer to the Eylea Patient Information Leaflet (PIL). You can access the PIL by asking your doctor or via the Israeli Drug Registry in the following link:
<https://israel drugs.health.gov.il/#!/byDrug>

Reporting about side effects

Side effects can be reported to the Ministry of Health using the portal for reporting side effects which can be found on the Ministry of Health website: www.health.gov.il

Or via the link: <http://sideeffects.health.gov.il/>

Additionally, side effects and product quality complaints can be reported to Bayer Israel:

E-mail: dsisrael@bayer.com, Fax: 09-7626741

What if I have concerns or questions?

If you have any concerns or questions, your doctor or nurse are the best people to speak to. They are very experienced and they know your individual situation so can provide you with the answers you need.

Your eye care clinic is: _____

Contact: _____

Telephone: _____

Address: _____

Email: _____

Clinic Stamp: _____



This guide and its content were approved by
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