EYLEA®

Patient Guide

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This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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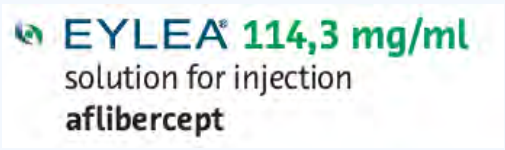
Your guide to EYLEA®



EYLEA is used to treat wet age-related macular degeneration (wAMD)

The booklet has been produced for people who have been prescribed 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 and in diabetic macular edema (abbreviated as DME). Your doctor may give you either the EYLEA 2 mg dose or the EYLEA 8 mg dose, depending on your situation. If the EYLEA 2 mg dose is given, your doctor will use the EYLEA 40 mg/ml solution. If the EYLEA 8 mg dose is given, your doctor will use the EYLEA 114.3 mg/ml solution.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed EYLEA because you have been diagnosed with wet age-related macular degeneration, or wAMD.

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. Wet AMD 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.

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. It is available in a 2 mg dose and an 8 mg dose. Your doctor will determine which dose is best suited to meet your individual

situation. 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 wAMD.

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 very little 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 benefit outweighs the risk to the foetus. 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. 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.

How can I get ready for my EYLEA appointment?

Your doctor may ask you to use eye drops for a few days before your 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	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)	Blurry vision Seeing shadows Less vivid lines and shapes

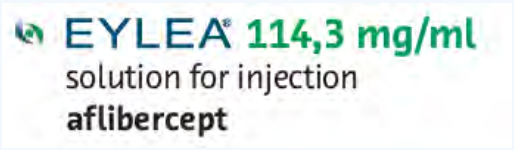
	Colour vision changes (e.g. colours look 'washed out')
Increase in pressure in the eye	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
A detachment or tear of a layer of the retina	Sudden flashes of light A sudden appearance or an increase of floaters A curtain 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).

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 guide to EYLEA®



EYLEA is used to treat Diabetic Macular Oedema (DME)

The booklet has been produced for people who have been prescribed EYLEA (aflibercept solution for injection) for the treatment of DME. The EYLEA 2 mg dose and the EYLEA 8 mg dose have been studied in wet age-related macular degeneration (abbreviated as wAMD) and in DME. Your doctor may give you either the EYLEA 2 mg dose or the EYLEA 8 mg dose, depending on your situation. If the EYLEA 2 mg dose is given, your doctor will use the EYLEA 40 mg/mL solution. If the EYLEA 8 mg dose is given, your doctor will use the EYLEA 114.3 mg/mL solution.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed EYLEA because you have been diagnosed with diabetic macular oedema, or DME for short.

What is DME?

Diabetic macular oedema 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. Diabetesgoes 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.

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 help protect your vision. EYLEA blocks VEGF, and this action helps reduce the swelling in the retina and can lead to vision improvement and maintenance.

EYLEA is a solution (a liquid) that is injected into the eye. It is available in a 2 mg dose and an 8 mg dose. Your doctor will determine which dose is best suited to meet your individual situation. Your doctor will 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 DME.

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 very little 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 benefit outweighs the risk to the foetus. 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. 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.

How can I get ready for my EYLEA appointment?

Your doctor may ask you to use eye drops for a few days before your 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	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)	Blurry vision Seeing shadows Less vivid lines and shapes Colour vision changes (e.g. colours look 'washed out')
Increase in pressure in the eye	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
A detachment or tear of a layer of the retina	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).

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 guide to EYLEA®

EYLEA is used to treat macular oedema secondary to Central Retinal Vein Occlusion (CRVO)

The booklet has been produced for people who have been prescribed the EYLEA 2 mg dose (aflibercept solution for injection) for the treatment of CRVO. The EYLEA 2 mg dose and the EYLEA 8 mg dose have been studied in wet age-related macular degeneration (abbreviated as wAMD) and in diabetic macular edema (abbreviated as DME). The EYLEA 8 mg dose has not been studied in CRVO.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed EYLEA because you have been diagnosed with macular oedema secondary to central retinal vein occlusion, or 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.

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 swelling 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 treatment of CRVO, EYLEA is available in a 2 mg dose. 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 CRVO.

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 very little information about the safety of using EYLEA in pregnant women. EYLEA 2 mg should not be used during pregnancy, unless the benefit outweighs the risk to the

foetus. Discuss this with your doctor before treatment with EYLEA. Women of childbearing potential should use effective contraception during their treatment and for at least three months after the last injection of EYLEA. 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.

How can I get ready for my EYLEA appointment?

Your doctor may ask you to use eye drops for a few days before your 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.

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	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)	Blurry vision Seeing shadows Less vivid lines and shapes Colour vision changes (e.g. colours look 'washed out')

Increase in pressure in the eye	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
A detachment or tear of a layer of the retina	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).

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 guide to EYLEA®

EYLEA is used to treat macular oedema secondary to Branch Retinal Vein Occlusion (BRVO)

The booklet has been produced for people who have been prescribed the EYLEA 2 mg dose (aflibercept solution for injection) for the treatment of BRVO. The EYLEA 2 mg dose and the EYLEA 8 mg dose have been studied in wet age-related macular degeneration (abbreviated as wAMD) and in diabetic macular edema (abbreviated as DME). The EYLEA 8 mg dose has not been studied in BRVO.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed EYLEA because you have been diagnosed with macular oedema secondary to branch retinal vein occlusion, or 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.

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 swelling 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 treatment of BRVO, EYLEA is available in a 2 mg dose. Your doctor will also recommend a treatment schedule for you and it is important that you follow it.

Who is EYLEA for?

EYLEA is for people who have been diagnosed with BRVO.

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 very little information about the safety of using EYLEA in pregnant women. EYLEA 2 mg should not be used during

pregnancy, unless the benefit outweighs the risk to the foetus. Discuss this with your doctor before treatment with EYLEA. Women of childbearing potential should use effective contraception during their treatment and for at least three months after the last injection of EYLEA. 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.

How can I get ready for my EYLEA appointment?

Your doctor may ask you to use eye drops for a few days before your 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.

In the next few days you may get a bloodshot eye or see moving spots in your vision. Both of 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.

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	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)	Blurry vision Seeing shadows Less vivid lines and shapes Colour vision changes (e.g. colours look 'washed out')

Increase in pressure in the eye	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
A detachment or tear of a layer of the retina	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).

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 guide to EYLEA®

EYLEA is used to treat myopic Choroidal Neovascularization (mCNV)

The booklet has been produced for people who have been prescribed the EYLEA 2 mg dose (aflibercept solution for injection) for the treatment of mCNV. The EYLEA 2 mg dose and the EYLEA 8 mg dose have been studied in wet age-related macular degeneration (abbreviated as wAMD) and in diabetic macular edema (abbreviated as DME). The EYLEA 8 mg dose has not been studied in
mCNV.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed EYLEA because you have been diagnosed with myopic choroidal neovascularization, or 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 eye ball 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 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, and it is involved in making these new blood vessels in the eye. These new blood vessels can cause leakage of blood and fluid into the eye, which leads to blurred or distorted central vision.

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 swelling 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 treatment of mCNV, EYLEA is available in a 2 mg dose. Your doctor will also recommend a treatment schedule for you and it is important that you follow it.

Who is EYLEA for?

EYLEA is for people who have been diagnosed with mCNV.

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 very little information about the safety of using EYLEA in pregnant women. EYLEA 2 mg should not be used during pregnancy, unless the benefit outweighs the risk to the foetus. Discuss this with your doctor before treatment with EYLEA. Women of childbearing potential should use effective contraception during their treatment and for at least three months after the last injection of EYLEA. 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.

How can I get ready for my EYLEA appointment?

Your doctor may ask you to use eye drops for a few days before your 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.

In the next few days you may get a bloodshot eye or see moving spots in your vision. Both of 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.

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	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)	Blurry vision Seeing shadows Less vivid lines and shapes

	Colour vision changes (e.g. colours look 'washed out')
Increase in pressure in the eye	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
A detachment or tear of a layer of the retina	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).

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.

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

Please report any adverse events to

The National Pharmacovigilance and Drug Safety Centre:
SFDA call center: 19999
E-Mail: npc.drug@sfda.gov.sa
Online: https://ade.sfda.gov.sa/Home/Report

Or

For further details, Please contact:

Bayer Saudi Arabia LLC
King Road Tower – King Abdul Aziz Road
Jeddah, Saudi Arabia
Tel.: +966 126573015
Web: https://middleeast.bayer.com
* **For Medical Inquiries:** med-info.me@bayer.com
** **For Safety Reporting:** www.safetrack-public.bayer.com or pv.me@bayer.com

*** *Information sent to the above contact details is subject to* ***Bayer Privacy Statement*** *(https://me-privacy.baywsf.com/) and/or* ***Bayer Privacy Statement for Pharmacovigilance Data*** *(https://www.bayer.com/en/privacy-statement-pv) and might be transferred outside your country, including but not limited to, transfer outside the United Arab Emirates & Saudi Arabia*

Package leaflet: Information for the patient

EYLEA® 114.3 mg/ml

solution for injection

aflibercept

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Eylea is and what it is used for

What Eylea is

Eylea contains the active substance aflibercept. It belongs to a group of medicines called antineovascularistion agents.

Your doctor will inject Eylea into your eye to treat eye disorders in adults called:
- wet age-related macular degeneration (wet AMD)
- visual impairment due to diabetic macular oedema (DME).

These disorders affect the macula. The macula is the central part of the light sensitive membrane at the back of the eye. It is responsible for clear vision.

Wet AMD is caused when abnormal blood vessels form and grow below the macula. The abnormal blood vessels may leak fluid or blood into the eye. Leaky blood vessels that cause swelling of the macula cause DME. Both disorders may impact your vision.

How Eylea works

Eylea stops growth of new abnormal blood vessels in the eye. Eylea can help to stabilise and often improve vision.

2. What you need to know before you receive Eylea

You will not receive Eylea if you
- are allergic to aflibercept or any of the other ingredients of this medicine (listed in section 6)
- have an infection in or around the eye
- have pain or redness in your eye (severe eye inflammation).

Warnings and precautions

Talk to your doctor **before receiving** Eylea if you:
- have glaucoma – an eye condition caused by high pressure in the eye
- have a history of seeing flashes of light or dark floating spots and if their size or number suddenly increases
- had eye surgery in the last 4 weeks or eye surgery is planned in the next 4 weeks.

Tell your doctor **immediately if** you develop:
- redness of the eye
- eye pain
- increased discomfort
- blurred or decreased vision
- increased sensitivity to light

These may be symptoms of an inflammation or infection and your doctor may stop giving you Eylea.

Furthermore, it is important for you to know that:
- the safety and efficacy of Eylea when administered to both eyes at the same time have not been studied and such use may increase risk of experiencing side effects.
- injections with Eylea may cause an increase in eye pressure in some patients within 60 minutes of the injection. Your doctor will monitor this after each injection.
- your doctor will check for other risk factors that may increase the chance of a tear or detachment of one of the layers at the back of the eye. In such cases your doctor will give you Eylea with caution.
- women who could become pregnant must use effective birth control during treatment and for at least 4 months after the last injection of Eylea.

The use of substances similar to those contained in Eylea is potentially related to the risk of blood clots blocking blood vessels, which may lead to heart attack or stroke. Theoretically, this could also happen after an injection of Eylea into the eye. If you had a stroke, a mini-stroke or a heart attack within the last 6 months, your doctor will give you Eylea with caution.

Children and adolescents

The use of Eylea in children or adolescents under 18 has not been studied because the diseases indicated occur mainly in adults. Therefore, its use in this age group is not relevant.

Other medicines and Eylea

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
- Women who could become pregnant must use effective birth control during treatment and for at least 4 months after the last injection of Eylea.
- There is no experience on the use of Eylea in pregnant women. Women should not receive Eylea during pregnancy unless the potential benefit to the woman outweighs the potential risk to the unborn child.
- Small amounts of Eylea may pass into human milk. The effect on breast-fed newborns/infants are unknown. Eylea is not recommended during breast-feeding.

Therefore, if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this medicine.

Driving and using machines

After receiving Eylea, you may experience some temporary vision problems. Do not drive or use machines as long as these last.

3. How Eylea will be given

The recommended dose is 8 mg aflibercept per injection.
- You will receive 1 injection every month for the first 3 months.
- After that, you may receive injections up to every 5 months. Your doctor will decide on the frequency based on the condition of your eye.

Method of administration

Your doctor will inject Eylea into your eye (intravitreal injection).

Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor will give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent pain from the injection.

If you missed a dose of Eylea

Make a new appointment with your doctor as soon as possible.

Before stopping Eylea treatment

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

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects of Eylea injection are either from the medicine itself or from the injection procedure and mostly affect the eye.

Some side effects could be serious

Contact your doctor immediately if you have any of the following:
- common side effect, which may affect up to 1 in 10 people
  - clouding of the lens (cataract)
  - bleeding in the back of the eye (retinal haemorrhage)
  - increase of pressure inside the eye
  - bleeding inside the eye (vitreous haemorrhage)
- uncommon side effect, which may affect up to 1 in 100 people
  - certain forms of clouding of the lens (cataract subcapsular)
  - detachment, tear or bleeding of the light-sensitive layer at the back of the eye, resulting in flashes of light with floaters, sometimes progressing to a loss of vision (retinal detachment or tear)

Other possible side effects

Common (may affect up to 1 in 10 people):
- moving spot in your vision (vitreous floaters)
- detachment of the gel-like substance inside the eye (vitreous detachment)
- reduced sharpness of vision
- eye pain
- bleeding inside the eye (conjunctival haemorrhage)
- damage to the clear layer of the eyeball in front of the iris (punctate keratitis)

Uncommon (may affect up to 1 in 100 people):
- allergic reactions
- detachment or tear of one of the layers in the back of the eye, resulting in flashes of light with floaters, sometimes progressing to a loss of vision (retinal pigment epithelial tear/detachment;)
- inflammation in the iris, of other parts of the eye, or the gel-like substance inside the eye (iritis, iridocyclitis, vitritis)
- certain forms of clouding of the lens (cataract cortical/nuclear)
- damage to the front layer of the eyeball (corneal abrasion/erosion)
- blurred vision
- eye pain at injection site
- a feeling of having something in the eye
- increased tear production
- bleeding at the injection site
- redness of the eye

Rare (may affect up to 1 in 1 000 people):
- blindness
- inflammation of other parts of the eye (uveitis)
- swelling of the eyelid
- irritation at injection site
- swelling of the front layer of the eyeball (corneal oedema)

Besides the above the following side effects may occur although they have not been reported in clinical studies:
- redness of the eye (ocular hyperaemia)
- degeneration of the light sensitive membrane at the back of the eye (retinal degeneration)
- abnormal sensation in eye
- clouding of the lens (lenticular opacities), clouding of the lens due to injury (traumatic cataract)
- damage to the surface of the clear front layer of the eye (corneal epithelium defect)
- inflammation of other parts of the eye (anterior chamber flare)
- eyelid irritation
- serious inflammation or infection inside the eye (endophthalmitis)
- pus in the eye (hypopyon)
- severe allergic reactions

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

Saudi Arabia:
The National Pharmacovigilance Centre (NPC).
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Other Countries:
Please contact the relevant competent authority

5. How to store Eylea
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- Keep the vial in the outer carton in order to protect from light.

6. Contents of the pack and other information

What Eylea contains
- The active substance is aflibercept. 1 ml solution contains 114.3 mg aflibercept. Each vial contains 0.263 ml. This provides a usable amount to deliver a single dose of 0.07 ml containing 8 mg aflibercept.
- The other ingredients are: sucrose, arginine hydrochloride, histidine hydrochloride monohydrate, histidine, polysorbate 20, water for injections.

What Eylea looks like and contents of the pack

Eylea is a solution for injection (injection). The solution is colourless to pale yellow. Pack size: 1 vial + 1 filter needle.

Bulk manufacturer
Catalent Indiana, LLC
1300 South Patterson Drive,
Bloomington, IN 47403, USA.

Final Release
Bayer AG
Müllerstraße 178
13353 Berlin, Germany.

Marketing Authorisation Holder
Bayer AG
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany

This leaflet was last revised in January 2024.

The following information is intended for healthcare professionals only:

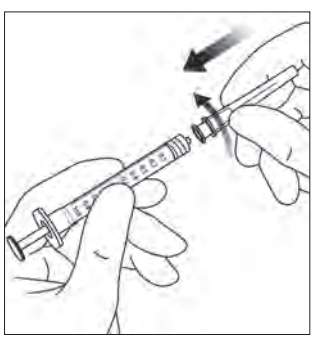
The vial is for single use in one eye only. Extraction of multiple doses from a single vial may increase the risk of contamination and subsequent infection.

Do not use if the package or its components are expired, damaged, or have been tampered with. Check the label on the vial to make sure you have the strength of Eylea that you intended to use. The 8 mg dose requires use of the Eylea 114.3 mg/ml vial.

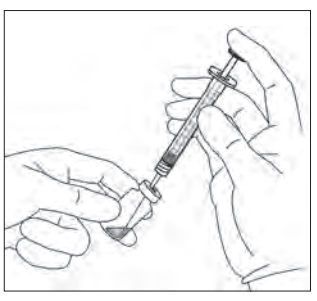
The intravitreal injection should be performed with a 30 G x ½ inch injection needle *(not included)*.

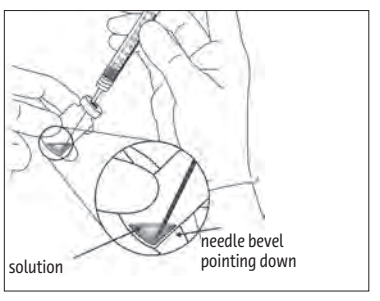
1. Prior to administration visually inspect the solution for injection.
   Do not use the vial if particulates, cloudiness, or discolouration are visible.
2. Remove the plastic cap and disinfect the outer part of the rubber stopper of the vial.

3. Use aseptic technique to carry out steps 3-10. Attach the filter needle supplied in the carton to a 1-ml sterile, Luer-lock syringe.

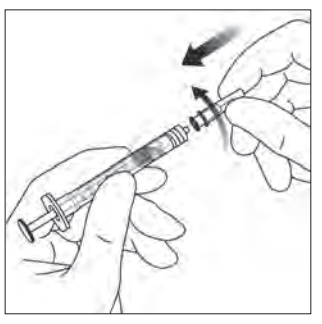


4. Push the filter needle into the centre of the vial stopper until the needle is completely inserted into the vial and the tip touches the bottom or bottom edge of the vial.
5. Withdraw all of the Eylea vial content into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. To deter the introduction of air, ensure the bevel of the filter needle is submerged into the liquid. Continue to tilt the vial during withdrawal keeping the bevel of the filter needle submerged in the liquid.

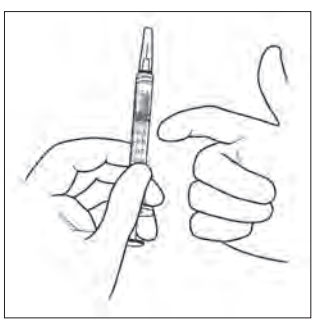




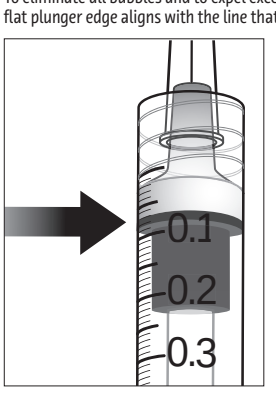
6. Ensure that the plunger rod is drawn sufficiently back when emptying the vial to completely empty the filter needle. After injection any unused product must be discarded.
7. Remove the filter needle and properly dispose of it.
   Note: The filter needle is **not** to be used for the intravitreal injection.
8. Firmly twist the 30 G x ½ inch injection needle onto the Luer-lock syringe tip.

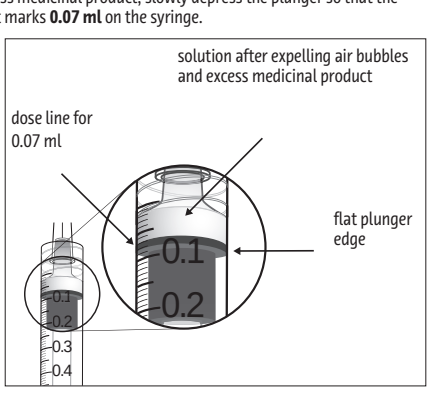


9. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



10. To eliminate all bubbles and to expel excess medicinal product, slowly depress the plunger so that the flat plunger edge aligns with the line that marks **0.07 ml** on the syringe.





Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

This is a Medicament
- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

EYLEA® 114.3 mg/ml

90357683

Bayer

EYLEA®

Package Leaflet: Information for the patient

Eylea 40 mg/mL solution for injection in a pre-filled syringe

aflibercept

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT EYLEA IS AND WHAT IT IS USED FOR

Eylea is a solution which is injected into the eye to treat eye conditions in adults called

- neovascular (wet) age-related macular degeneration (wet AMD),
- impaired vision due to macular oedema secondary to retinal vein occlusion (branch RVO (BRVO) or central RVO (CRVO)),
- impaired vision due to diabetic macular oedema (DME).
- impaired vision due to myopic choroidal neovascularisation (myopic CNV).

Aflibercept, the active substance in Eylea, blocks the activity of a group of factors, known as Vascular Endothelial Growth Factor A (VEGF-A) and Placental Growth Factor (PlGF).

In patients with wet AMD and myopic CNV, these factors, in excess are involved in the abnormal formation of new blood vessels in the eye. These new blood vessels can cause the leak of blood components into the eye and eventual damage to tissues in the eye responsible for vision.

In patients with CRVO, a blockage occurs in the main blood vessel that transports blood away from the retina. VEGF levels are elevated in response causing the leakage of fluid into the retina and thereby causing a swelling of the macula, (the portion of the retina responsible for fine vision), which is called macular oedema. When the macula swells with fluid, central vision becomes blurry.

In patients with BRVO, one or more branches of the main blood vessel that transports blood away from the retina is blocked. VEGF levels are elevated in response causing the leakage of fluid into the retina and thereby causing macular oedema.

Diabetic macular oedema is a swelling of the retina occurring in patients with diabetes due to leaking of fluid from blood vessels within the macula. The macula is the portion of retina responsible for fine vision. When the macula swells with fluid, central vision becomes blurry.

Eylea has been shown to stop the growth of new abnormal blood vessels in the eye which often leak fluid or bleed. Eylea can help to stabilise, and in many cases, improve the vision loss related to wet AMD, CRVO, BRVO, DME and myopic CNV.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN EYLEA

You will not be given Eylea:

- if you are allergic to aflibercept or any of the other ingredients of this medicine (listed in section 6)
- if you have an active or suspected infection in or around the eye (ocular or periocular infection)
- if you have severe inflammation of the eye (indicated by pain or redness)

Warnings and precautions

Talk to your doctor before you are given Eylea:

- if you have glaucoma.
- if you have a history of seeing flashes of light or floaters and if you have a sudden increase of size and number of floaters.
- if surgery was performed or is planned on your eye within the previous or next four weeks.
- if you have a severe form of CRVO or BRVO (ischaemic CRVO or BRVO), treatment with Eylea is not recommended.

Furthermore, it is important for you to know that

- the safety and efficacy of Eylea when administered to both eyes at the same time have not been studied and if used in this way may lead to an increased risk of experiencing side effects.
- injections with Eylea may cause an increase in eye pressure (intraocular pressure) in some patients within 60 minutes of the injection. Your doctor will monitor this after each injection.
- if you develop an infection or inflammation inside the eye (endophthalmitis) or other complications, you may have eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, and increased sensitivity to light. It is important to have any symptoms diagnosed and treated as soon as possible.
- your doctor will check whether you have other risk factors that may increase the chance of a tear or detachment of one of the layers at the back of the eye (retinal detachment or tear, and retinal pigment epithelial detachment or tear), in which case Eylea must be given with caution.
- Eylea should not be used in pregnancy unless the potential benefit outweighs the potential risk to the unborn child.
- women of childbearing potential have to use effective contraception during treatment and for at least three further months after the last injection of Eylea.

The systemic use of VEGF inhibitors, substances similar to those contained in Eylea, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events) which may lead to heart attack or stroke.

There is a theoretical risk of such events following injection of Eylea into the eye. There are limited data on safety in treating patients with CRVO, BRVO, DME and myopic CNV who have had a stroke or a mini-stroke (transient ischaemic attack) or a heart attack within the last 6 months. If any of these apply to you, Eylea will be given with caution.

There is only limited experience in the treatment of

- patients with DME due to type I diabetes.
- diabetics with very high average blood sugar values (HbA1c over 12%).
- diabetics with an eye disease caused by diabetes called proliferative diabetic retinopathy.

There is no experience in the treatment of

- patients with acute infections.
- patients with other eye conditions such as a detachment of the retina or a hole in the macula.
- diabetics with uncontrolled high blood pressure.
- non-Asian patients with myopic CNV.
- patients previously treated for myopic CNV.
- patients with damage outside the central part of the macula (extrafoveal lesions) for myopic CNV.

If any of the above applies to you, your doctor will consider this lack of information when treating you with Eylea.

Children and adolescents

The use of Eylea in children or adolescents under 18 has not been studied because wet AMD, CRVO, BRVO, DME and myopic CNV occur mainly in adults. Therefore, its use in this age group is not relevant.

Other medicines and Eylea

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

- Women of childbearing potential have to use effective contraception during treatment and for at least three further months after the last injection of Eylea.
- There is no experience of using Eylea in pregnant women. Eylea should not be used during pregnancy unless the potential benefit outweighs the potential risk to the unborn child. If you are pregnant or planning to become pregnant, discuss this with your doctor before treatment with Eylea.
- Eylea is not recommended during breast-feeding as it is not known whether Eylea passes into human milk. Ask your doctor for advice before starting Eylea treatment.

Driving and using machines

After your injection with Eylea, you may experience some temporary visual disturbances. Do not drive or use machines as long as these last.

Important information about some of the ingredients of Eylea

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‚sodium-free'.

3. HOW YOU WILL BE GIVEN EYLEA

A doctor experienced in giving eye injections will inject Eylea into your eye under aseptic (clean and sterile) conditions.

The recommended dose is 2 mg aflibercept (0.05 mL).

Eylea is given as an injection into your eye (intravitreal injection).

Before the injection your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

wet AMD

Patients with wet AMD will be treated with one injection per month for three consecutive doses, followed by another injection after a further two months .

Your doctor will then decide whether the treatment interval between injections may be kept at every two months or be gradually extended in 2- or 4-weekly intervals if your condition has been stable. If your condition worsens, the interval between injections can be shortened.

Unless you experience any problems or are advised differently by your doctor, there is no need for you to see your doctor between the injections.

Macular oedema secondary to RVO (branch RVO or central RVO)

Your doctor will determine the most appropriate treatment schedule for you. You will start your treatment with a series of monthly Eylea injections.

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

Your doctor may decide to stop treatment with Eylea, if you are not benefiting from continued treatment.

Your treatment will continue with monthly injections until your condition is stable. Three or more monthly injections may be needed.

Your doctor will monitor your response to treatment and may continue your treatment by gradually increasing the interval between your injections to maintain a stable condition. If your condition starts to worsen with a longer treatment interval, your doctor will shorten the interval accordingly.

Based on your response to treatment your doctor will decide on the schedule for follow up examinations and treatments.

Diabetic macular oedema (DME)

Patients with DME will be treated with one injection per month for the first five consecutive doses followed by one injection every two months thereafter.

Unless you experience any problems or are advised differently by your doctor, there is no need for you to see your doctor between the injections.

After the first 12 months of treatment with Eylea, the treatment interval may be extended based on your doctor's examination. Your doctor will decide on the schedule for follow up examinations.

Your doctor may decide to stop treatment with Eylea if it is determined that you are not benefiting from continued treatment.

Myopic CNV

Patients with myopic CNV will be treated with one single injection. You will receive further injections only if your doctor's examinations reveal that your condition has not improved.

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

If your condition goes away and then comes back, your doctor may re-start the treatment.

Your doctor will decide on the schedule for follow up examinations.

If a dose of Eylea is missed

Make a new appointment for an examination and injection.

Stopping treatment with Eylea

Consult your doctor before stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions (hypersensitivity) could potentially occur. **These may be serious and require that you contact your doctor immediately.**

With administration of Eylea, there may be some side effects affecting the eyes which are due to the injection procedure. Some of these may be **serious** and include **blindness, a serious infection or inflammation inside the eye** (endophthalmitis), **detachment, tear or bleeding of the light-sensitive layer at the back of the eye** (retinal detachment or tear), **clouding of the lens** (cataract), **bleeding in the eye** (vitreous haemorrhage), **detachment of the gel-like substance inside the eye from the retina** (vitreous detachment) and **increase of pressure inside the eye**, see section 2. These serious side effects affecting the eyes occurred in less than 1 in 1,900 injections in clinical studies.

If you experience a sudden decrease in vision, or an increase in pain and redness in your eye after your injection, **contact your doctor immediately.**

List of side effects reported:

The following is a list of the side effects reported to be possibly related to the injection procedure or to the medicine. Please do not get alarmed, you might not experience any of these. Always discuss any suspected side effects with your doctor.

Very common side effects (may affect more than 1 in 10 people):

- deterioration of eyesight
- bleeding in the back of the eye (retinal haemorrhage) bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye
- eye pain

Common side effects (may affect up to 1 in 10 people)**:**

- detachment or tear of one of the layers in the back of the eye, resulting in flashes of light with floaters sometimes progressing to a loss of vision (retinal pigment epithelial tear* /detachment, retinal detachment/tear)
- degeneration of the retina (causing disturbed vision)
- bleeding in the eye (vitreous haemorrhage)
- certain forms of clouding of the lens (cataract)
- damage to the front layer of the eyeball (the cornea)
- increase in eye pressure
- moving spots in vision (floaters)
- detachment of the gel-like substance inside the eye from the retina (vitreous detachment, resulting in flashes of light with floaters)
- a feeling of having something in the eye
- increased tear production
- swelling of the eyelid
- bleeding at the injection site
- redness of the eye

* Conditions known to be associated with wet AMD; observed in wet AMD patients only.

Uncommon side effects (may affect up to 1 in 100 people)**:**

- allergic reactions (hypersensitivity)**
- serious inflammation or infection inside the eye (endophthalmitis)
- inflammation in the iris or other parts of the eye (iritis, uveitis, iridocyclitis, anterior chamber flare)
- abnormal sensation in the eye
- eyelid irritation
- swelling of the front layer of the eyeball (cornea)

** Allergic reactions like rash, itching (pruritus), hives (urticaria), and a few cases of severe allergy (anaphylactic/anaphylactoid) reactions were reported

Rare side effects (may affect up to 1 in 1,000 people)**:**

- blindness
- clouding of the lens due to injury (traumatic cataract),
- inflammation of the gel-like substance inside the eye
- pus in the eye

In the clinical trials, there was an increased incidence of bleeding from small blood vessels in the outer layers of the eye (conjunctival haemorrhage) in patients with wet AMD receiving blood thinners. This increased incidence was comparable between patients treated with ranibizumab and Eylea.

The systemic use of VEGF inhibitors, substances similar to those contained in Eylea, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events) which may lead to heart attack or stroke. There is a theoretical risk of such events following injection of Eylea into the eye.

As with all therapeutic proteins, there is a possibility for an immune reaction (formation of antibodies) with Eylea.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

Saudi Arabia:
The National Pharmacovigilance Centre (NPC).
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Kuwait:
Drug &Food Control, Ministry of Health ,Kuwait
Tel.: +965-24811532
Fax: +965-24811507
Email : Adr_reporting@moh.gov.kw
Website: http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx

Other Countries:

Please contact the relevant competent authority

5. HOW TO STORE EYLEA

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- The unopened blister may be stored outside the refrigerator below 25 °C for up to 24 hours.
- Store in the original package in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Eylea contains

- The active substance is: aflibercept.
  One pre-filled syringe contains an extractable volume of at least 0.09 mL, equivalent to at least 3.6 mg aflibercept. One pre-filled syringe delivers a dose of 2 mg aflibercept in 0.05 mL.
- The other ingredients are: polysorbate 20 (E 432), sodium dihydrogen phosphate monohydrate (for pH adjustment), disodium hydrogen phosphate heptahydrate (for pH adjustment), sodium chloride, sucrose, water for injections.

What Eylea looks like and contents of the pack

Eylea is a solution for injection (injection) in a pre-filled syringe. The solution is colourless to pale yellow.

Pack size of 1 pre-filled syringe.

Bulk manufacturer

Regeneron Pharmaceuticals Inc
81 Columbia Turnpike
Rensselaer, New York 12144, United States

Final Release

Bayer AG
Müllerstraße 178
13353 Berlin, Germany.

Marketing Authorisation Holder

Bayer AG
51368 Leverkusen, Germany.

This leaflet was last revised in July 2021.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

The following information is intended for healthcare professionals only:

The pre-filled syringe should only be used **for the treatment of a single eye**.

Do not open the sterile pre-filled syringe blister outside the clean administration room.

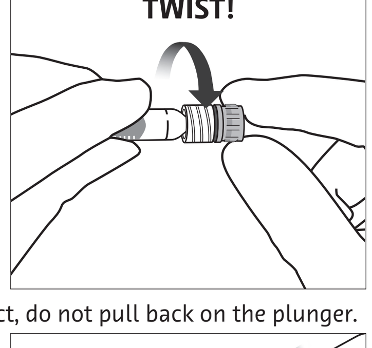
The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL). The excess volume must be discarded prior to administration. The solution should be inspected visually for any foreign particulate matter and/or discolouration or any variation in physical appearance prior to administration. In the event of either being observed, discard the medicinal product.

The unopened blister may be stored outside the refrigerator below 25° C for up to 24 hours. After opening the blister, proceed under aseptic conditions.

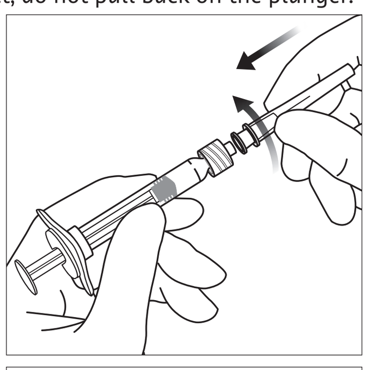
For the intravitreal injection, a 30 G x ½ inch injection needle should be used.

Instructions for use of pre-filled syringe:

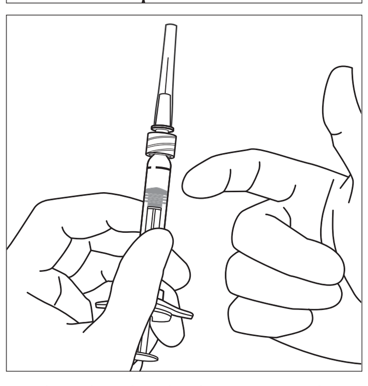
1. When ready to administer Eylea, open the carton and remove the sterilised blister. Carefully peel open the blister ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.
2. Using aseptic technique, remove the syringe from the sterilised blister.
3. To remove the syringe cap, hold the syringe in one hand while using the other hand to grasp the syringe cap with the thumb and fore finger. Please note: You should twist off (do not snap off) the syringe cap.



4. To avoid compromising the sterility of the product, do not pull back on the plunger.
5. Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip

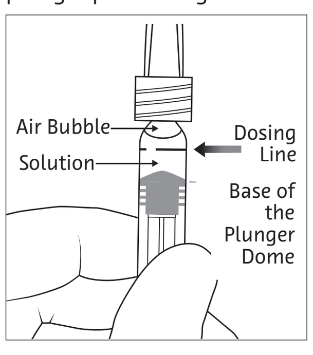


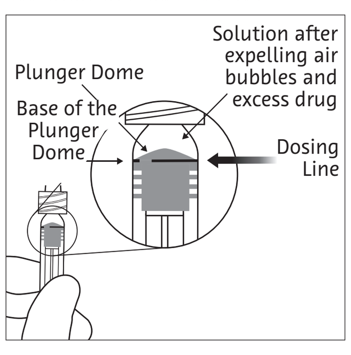
6. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



7. Eliminate all bubbles and expel excess medicinal product by slowly depressing the plunger to align the base of the plunger dome (not the tip of the dome) with the black dosing line on the syringe (equivalent to 0.05 mL i.e. 2 mg aflibercept).

   Note: This accurate positioning of the plunger is very important, because incorrect plunger positioning can lead to delivering more or less than the labelled dose.





8. Inject while pressing the plunger carefully and with constant pressure. Do not apply additional pressure once the plunger has reached the bottom of the syringe. **Do not administer any residual solution observed in the syringe.**
9. The pre-filled syringe is for single use only. Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection.

   Any unused medicinal product or waste material should be disposed of in accordance with local requirements.