Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Package Leaflet: Information for the adult patient

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

USE IN ADULTS

Please find information for guardians of babies born prematurely on the other side of this leaflet.

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 has 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 (injecting directly into the bloodstream) of VEGF inhibitors, substances like 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 and adolescents under 18 years of age for indications other than ROP has not been studied. For the treatment of babies born prematurely with retinopathy of prematurity (ROP), please see the other side of this leaflet.

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.

- Small amounts of Eylea may pass into human milk. The effects on breast-fed newborns/infants are unknown. Eylea is not recommended during breast-feeding. If you are a breastfeeding woman, discuss this with your doctor before treatment with Eylea.

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 healthcare professional 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 healthcare professional will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your healthcare professional 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.

Treatment interval may be kept at every two months or adjusted to your condition, 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.

Detailed instructions for use are given at the end of the leaflet under "How to prepare and administer Eylea to adults".

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)
    - *observed in patients with wet AMD
- 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

Uncommon side effects (may affect up to 1 in 100 people):
- allergic reactions (hypersensitivity)**
    - **rash, itching, hives, and a few cases of severe allergy (anaphylactic/anaphylactoid) reactions were reported.
- 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)

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 (injecting directly into the bloodstream) of VEGF inhibitors, substances like 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. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

Marketing Authorisation Holder
Bayer plc
400 South Oak Way
Reading
RG2 6AD

Manufacturer
Bayer AG
Müllerstraße 178
13353 Berlin
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder:
Bayer plc
Tel: +44-(0)118 206 3000

This leaflet was last revised in 09/2023

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The following information is intended for healthcare professionals only:

How to prepare and administer Eylea to adults
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.

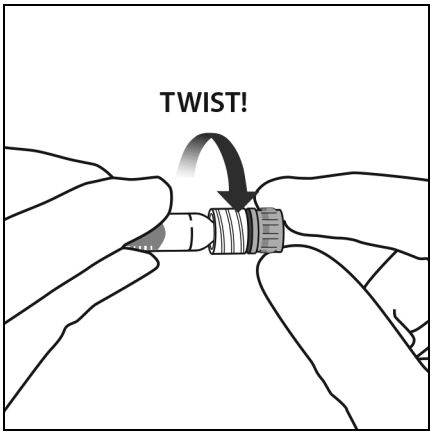
The unopened blister may be stored outside the refrigerator below 25°C for up to 24 hours. After opening the blister, proceed under aseptic conditions.
For the intravitreal injection, a 30 G x ½ inch injection needle should be used.

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.

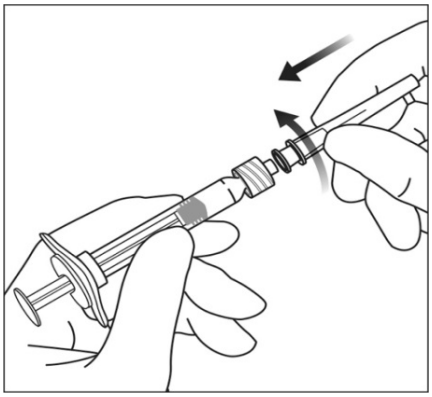
2. Using aseptic technique, remove the syringe from the sterilised blister.

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.

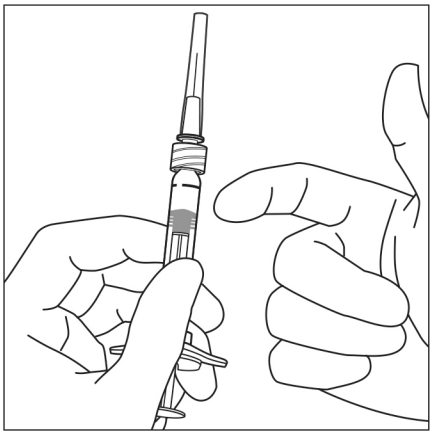


4. To avoid compromising the sterility of the product, do not pull back on the plunger.

5. Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip.

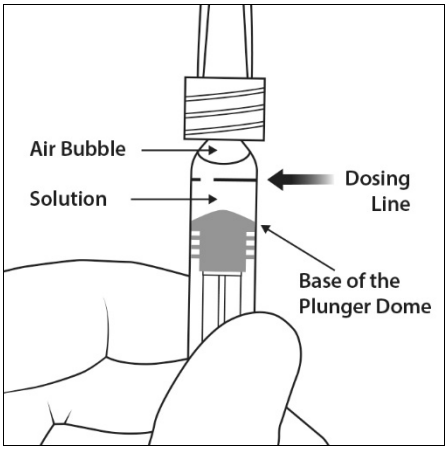


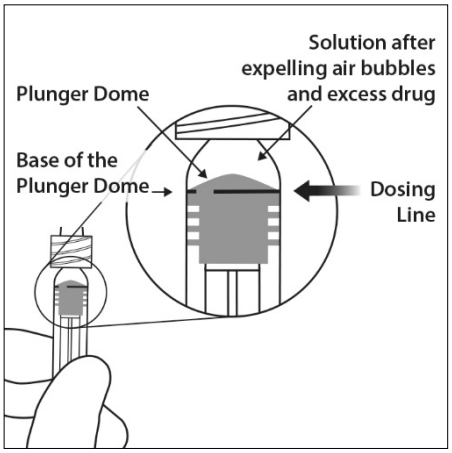
6. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



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 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.

Package Leaflet: Information for guardians of babies born prematurely

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

USE IN BABIES BORN PREMATURELY

Please find information on the use in adults on the other side of this leaflet.

Read all of this leaflet carefully before the baby is 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 the baby's doctor.
- If you notice any symptoms of side effects, talk to the baby's doctor. This includes any possible symptoms and 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. Eylea belongs to a group of medicines that block the activity of a group of factors, known as Vascular Endothelial Growth Factor A (VEGF-A) and Placental Growth Factor (PlGF). It contains the active substance called aflibercept.

Eylea is used in babies born prematurely to treat an eye condition called retinopathy of prematurity (ROP). Babies with ROP have abnormal growth of new blood vessels in the back of the eye (retina) induced by VEGF. This may cause vision impairment and in severe cases permanent blindness.

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 ROP.

2. What you need to know before the baby is given Eylea

The baby will not be given Eylea if he or she
- is **allergic** to aflibercept or any of the other ingredients of this medicine (listed in section 6).
- has an active or suspected infection in or around the eye (ocular or periocular infection).
- has severe inflammation of the eye (indicated by pain or redness).

Warnings and precautions
Talk to the baby's doctor before the baby is given Eylea

- if surgery was performed or is planned on the baby's eye within the previous or next four weeks.

Furthermore, it is important for you to know that

- injections with Eylea may cause an increase in eye pressure (intraocular pressure) in some patients within 60 minutes of the injection. The baby's doctor will monitor this after each injection.

- if the baby develops an infection or inflammation inside the eye (endophthalmitis) or other complications, the baby may have **redness/irritation of the eye**, **ocular discharge**, **lid swelling** and **increased sensitivity to light**. It is important to have any symptoms diagnosed and treated as soon as possible. **Please tell the baby's doctor immediately if the baby develops any signs or symptoms outlined.**
- the baby's doctor will check whether the baby has 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), in which case Eylea must be given with caution.

The systemic use (injecting directly into the bloodstream) of VEGF inhibitors, substances like 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 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 (the portion of the retina responsible for fine vision)

If either of the above applies, the baby's doctor will decide whether to treat the baby with Eylea.

Other medicines and Eylea
Tell the baby's doctor if the baby is receiving, has recently received or might receive any other medicines.

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 the baby will be given Eylea

A doctor experienced in giving eye injections will inject Eylea into the baby's eyes under aseptic (clean and sterile) conditions.

The recommended dose is 0.4 mg aflibercept (0.01 mL).
Eylea is given as an injection into the baby's eye (intravitreal injection).

Before the injection the baby's doctor will use a disinfectant eyewash to clean the baby's eye carefully to prevent infection. The doctor will also apply a medicine that blocks out sensation (local anaesthetic). This will reduce or prevent any pain from the injection.

The treatment is started with a single injection per eye and may be given into the second eye on the same day. The baby's doctor will monitor the condition of the baby's eye(s). Depending on how the baby responds to the treatment, the doctor will decide if and when further treatment is needed. The treatment interval between the 2 doses injected into the same eye should be at least 4 weeks.

Detailed instructions for use are given at the end of the leaflet under "How to prepare and administer Eylea to preterm infants".

Stopping treatment with Eylea
Treatment may be a single injection per affected eye, or a further injection may be required. The baby's doctor will advise on how long the baby should be treated with Eylea.

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

4. Possible side effects

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

Side effects observed in babies born prematurely

Side effects reported in more than one baby born prematurely were**:**
- **detachment of the layer in the back of the eye** (retinal detachment)
- **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 (conjunctival haemorrhage)
- **bleeding at the injection site** (injection site haemorrhage)
- **increase in eye pressure**
- **swelling of the eyelid** (eyelid oedema)**.**

Side effects observed in adults

These side effects may also occur in babies born prematurely:
- **allergic reactions** (hypersensitivity) could potentially occur. **These may be serious and require that you contact the baby's doctor immediately.**

Side effects affecting the eyes due to the injection procedure 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)
- **increase of pressure inside the eye** (intraocular pressure increased), see section 2.

These serious side effects affecting the eyes occurred in less than 1 in 1,900 injections in clinical studies in adults.

It is important to identify and treat serious side effects such as infection inside the eye or retinal detachment as soon as possible.
Tell the baby's doctor immediately if you notice symptoms in the baby's eye after injection such as
- **redness/irritation,**
- **ocular discharge**
- **lid swelling**
- **increased sensitivity to light**

List of other side effects reported in adults

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, the baby might not experience any of these. Always discuss any suspected side effects with the baby's 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)
    - *observed in patients with wet age-related macular degeneration (AMD)
- 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

Uncommon side effects (may affect up to 1 in 100 people):
- allergic reactions (hypersensitivity)**
    - ** rash, itching, hives, and a few cases of severe allergy (anaphylactic/anaphylactoid) reactions were reported.
- 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)

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

The systemic use (injecting directly into the bloodstream) of VEGF inhibitors, substances like 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.

If you have any questions about any side effects, ask the baby's doctor.

Reporting of side effects
If you observe any side effects in the baby, talk to the baby's doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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 25ºC 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 contains more than the recommended single dose of 0.4 mg aflibercept in 0.01 mL. The PICLEO paediatric dosing device in combination with the pre-filled syringe must be used for administration of a single dose of 0.4 mg aflibercept in 0.01 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.

Marketing Authorisation Holder

Bayer plc
400 South Oak Way
Reading
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Manufacturer

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The following information is intended for healthcare professionals only:

How to prepare and administer Eylea to preterm infants

The pre-filled syringe should only be used **for the treatment of a single eye.** Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection.

Do not open the sterile pre-filled blister outside the clean administration room. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

The pre-filled syringe contains more than the recommended dose of 0.4 mg aflibercept (equivalent to 0.01 mL). For treatment of preterm infants, the PICLEO paediatric dosing device in combination with the pre-filled syringe must be used for administration of a single dose of 0.4 mg aflibercept (equivalent to 0.01 mL). See following section "***Instructions for use of pre-filled syringe***".

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 ºC 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
To prepare the pre-filled syringe for administration to preterm infants, follow the steps 1 and 2 below and then adhere to the instructions for use included in the package of the PICLEO paediatric dosing device.

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.