Package leaflet: Information for the patient

EYLEA® 114.3 mg/ml solution for injection

aflibercept

The name of your medicine is EYLEA 114.3 mg/ml solution for injection but will be referred to as Eylea throughout 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

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 (DMO).

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 DMO. 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 limited 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 healthcare professional will inject Eylea 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 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/ nuclear)
  - 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):
- allergic reactions
- 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, corneal abrasion)

Uncommon (may affect up to 1 in 100 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)
- inflammation in the iris, of other parts of the eye, or the gel-like substance inside the eye (uveitis, iritis, iridocyclitis, vitritis)
- certain forms of clouding of the lens (cataract cortical)
- damage to the front layer of the eyeball (corneal 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
- swelling of the eyelid
- redness of the eye (ocular hyperaemia)
- irritation at injection site

Rare (may affect up to 1 in 1 000 people):
- swelling of the front layer of the eyeball (corneal oedema)
- clouding of the lens (lenticular opacities)
- degeneration of the light sensitive membrane at the back of the eye (retinal degeneration)
- eyelid irritation

Besides the above the following side effects may occur although they have not been reported in clinical studies:
- abnormal sensation in eye
- 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)
- serious inflammation or infection inside the eye (endophthalmitis)
- blindness
- clouding of the lens due to injury (traumatic cataract)
- 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. 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 - 8 °C). Do not freeze.
- The unopened vial may be stored outside the refrigerator below 25 °C for up to 24 hours.
- Keep the vial in the outer carton in order to protect from light.
- If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away 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. 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.

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Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK
For any information about this medicine, please contact the Product Licence Holder on www.orifarm.com/uk
Or phone: (+44) 1923 204333

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, Czech Republic

Manufactured by Bayer AG, Müllerstrasse 178, 13353 Berlin, Germany

EYLEA 114.3 mg/ml solution for injection
PL 45985/1019

POM

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

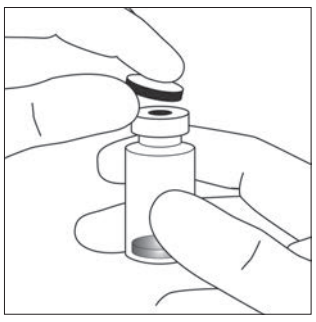
The following information is intended for healthcare professionals only:
The vial is for single use in one eye only. Extraction of multiple doses from a single vial may increase the risk of contamination and subsequent infection.

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.

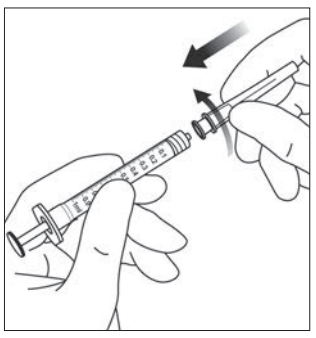
The intravitreal injection should be performed with a 30 G x ½ inch injection needle (not included). Use of a smaller size needle (higher gauge) than the recommended 30 G x ½ inch injection needle may result in increased injection forces.

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.

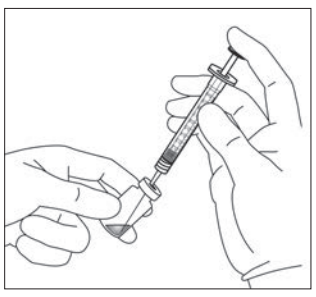


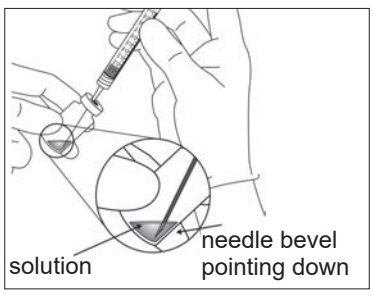
3. Use aseptic technique to carry out steps 3-10. Attach the filter needle supplied in the carton to a 1-ml sterile, Luer-lock syringe.



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.

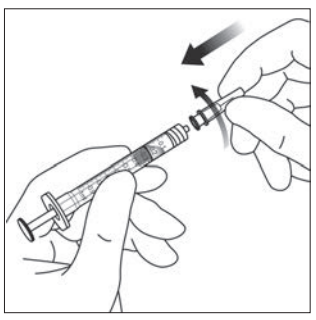




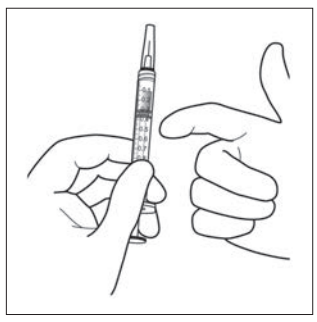
6. Ensure that the plunger rod is drawn sufficiently back when emptying the vial to completely empty the filter needle. After injection any unused product must be discarded.

7. Remove the filter needle and properly dispose of it.
Note: The filter needle is **not** to be used for the intravitreal injection.

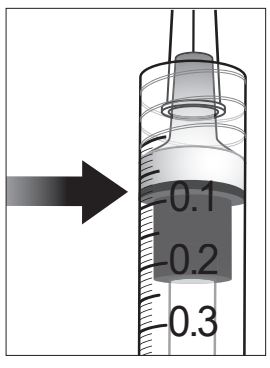
8. Firmly twist the 30 G x ½ inch injection needle onto the Luer-lock syringe tip.

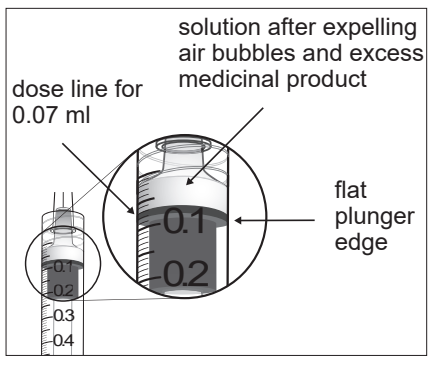


9. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



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.