

PRESCRIBER GUIDE TO INTRAVITREAL INJECTIONS WITH



EYLEA is indicated for the treatment of patients with neovascular (Wet) age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DMO) and visual impairment due to myopic choroidal neovascularisation (myopic CNV).

Please provide your patients with the EYLEA Patient Booklet including the audio CD (read out of the Patient Booklet) and the product Patient Information Leaflet.

For further information and additional details on EYLEA, please see the Summary of Product Characteristics (SmPC). This booklet has been produced by Bayer.

v.2 Review date: July 2018

DVD WALLET
PLACEHOLDER

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KEY SUMMARY INFORMATION

Indications

- Neovascular (wet) age-related macular degeneration (AMD)
- Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)
- Visual impairment due to diabetic macular oedema (DMO)
- Visual impairment due to myopic choroidal neovascularisation (myopic CNV)

Contraindications

- Hypersensitivity to aflibercept or to any of the excipients listed in section 6.1 of the SmPC
- Active or suspected ocular or periocular infection
- Active severe intraocular inflammation

Dosing recommendations

- The recommended dose for EYLEA is 2 mg aflibercept, equivalent to 50 microlitres

Selected instructions for storage and handling

- **Store EYLEA in the refrigerator (2°C to 8°C)**
- **Prior to usage**, the unopened vial may be **kept at room temperature (below 25°C) for up to 24 hours**
- In general, adequate **anaesthesia and asepsis**, including topical broad spectrum microbicide (e.g., povidone iodine applied to the periocular skin, eyelid, and ocular surface), have to be ensured

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- **Surgical hand disinfection, sterile gloves, a sterile drape, and a sterilised eyelid speculum** (or equivalent) are recommended
 - **Eye dilation prior to the injection procedure is not necessary**
 - EYLEA is **not licensed for multi-dose**, further compounding or vial splitting. Use of more than one injection from the vial **can lead to contamination and subsequent infection**

Special warnings and precautions for use

- Intravitreal injections, including those with EYLEA, have been associated with **endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract**
- **Increases in intraocular pressure** have been seen within 60 minutes of intravitreal injection, including those with EYLEA
- EYLEA is a therapeutic protein, there is a **potential for immunogenicity** with EYLEA
- Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of vascular endothelial growth factor (VEGF) inhibitors, and there is a theoretical risk that these may relate to VEGF inhibition
- **Women of childbearing potential** have to use effective contraception during treatment and for at least 3 months after the last intravitreal injection of EYLEA
- **EYLEA should not be used during pregnancy** unless the potential benefit outweighs the potential risk to the foetus

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- **EYLEA is not recommended during breast-feeding. A decision must be made whether to discontinue breast-feeding or to abstain from EYLEA therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman**

After the injection

- **Evaluate vision immediately after injection** (hand movement or finger counting)
- **Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure.** Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. Sterile equipment for paracentesis should be available for the case that paracentesis is required
- **Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis** (e.g. eye pain, redness of the eye, photophobia, blurring of vision) without delay

GENERAL INFORMATION

Before the start of treatment with EYLEA, a patient information booklet, including an audio CD and the Package Leaflet, must be provided to each patient who is prescribed EYLEA. The physician is responsible for providing the patient with these materials.

In addition, the implications of anti-VEGF treatment should be explained with respect to the patient's individual condition.

Specifically, any signs and symptoms of serious adverse events and when to seek medical attention should be discussed with the patient.

THERAPEUTIC INDICATIONS

EYLEA is indicated for adults for the treatment of

- Neovascular (wet) age-related macular degeneration (AMD)
- Visual impairment due to macular oedema secondary to branch or central retinal vein occlusion (BRVO or CRVO)
- Visual impairment due to diabetic macular oedema (DMO)
- Visual impairment due to myopic choroidal neovascularisation (myopic CNV)

PRODUCT INFORMATION

- EYLEA 40 mg/ml solution for injection
- EYLEA is for intravitreal injection only. It must only be administered by a qualified physician experienced in administering intravitreal injections
- The solution is a clear, colourless to pale yellow, and iso-osmotic solution
- 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 vial is for single use in one eye only
- EYLEA is not licensed for multi-dose, further compounding or vial splitting. Use of more than one injection from the vial can lead to contamination and subsequent infection

Qualitative and quantitative composition

- One vial contains an extractable volume of 100 microlitres, equivalent to 4 mg aflibercept. This provides a usable amount to deliver a single dose of 50 microlitres containing 2 mg aflibercept. The vial contains more than the recommended dose of 2 mg. **The extractable volume of the vial (100 microlitres) is not to be used in total. The excess volume should be expelled before injecting**

Special precautions for storage

- Store in a refrigerator (2°C to 8°C)
- Do not freeze
- Keep the vial in the outer carton in order to protect from light
- Prior to usage, the unopened vial of EYLEA may be stored at room temperature (below 25°C) for up to 24 hours
- After opening the vial, proceed under aseptic conditions

Dosing recommendations

- The recommended dose for EYLEA is 2 mg aflibercept, equivalent to 50 microlitres

For full details of the dosing schedule for wet AMD, macular oedema secondary to RVO, DMO and myopic CNV, please refer to section 4.2 of the SmPC.

Contraindications

- Hypersensitivity to aflibercept or to any of the excipients listed in section 6.1 of the SmPC
- Active or suspected ocular or periocular infection
- Active severe intraocular inflammation

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Please refer to section 4.4 and 4.6 of the SmPC for full information about special warnings and precautions for EYLEA treatment, including (but not limited to):

- Intravitreal injection-related reactions such as endophthalmitis
- Increase in intraocular pressure
- Immunogenicity
- Systemic effects
- Other:

Women of childbearing potential

Women of childbearing potential have to **use effective contraception during treatment** and **for at least 3 months** after the last intravitreal injection of EYLEA.

Pregnancy

Although the systemic exposure after ocular administration is very low, EYLEA should not be used during pregnancy unless the potential benefit outweighs the potential risk to the foetus.

Breast-feeding

EYLEA is not recommended during breast-feeding. A decision must be made whether to discontinue breast-feeding or to abstain from EYLEA therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

INSTRUCTIONS FOR USE/HANDLING

Injection preparation

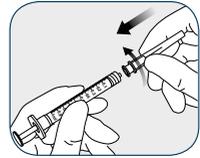
- Intravitreal injections must be carried out according to current medical standards and applicable guidelines by a qualified physician experienced in administering intravitreal injections
- In general, adequate anaesthesia and asepsis, including topical broad spectrum microbicide (e.g. povidone iodine applied to the periocular skin, eyelid and ocular surface), have to be ensured
- Eye dilation prior to the injection procedure is **not** necessary
- The vial is for single use in one eye only. EYLEA is not licensed for multi-dose, further compounding or vial splitting. Use of more than one injection from the vial can lead to contamination and subsequent infection
- Surgical hand disinfection, sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent) are recommended
- For the intravitreal injection, a 30 G x ½ inch injection needle should be used

Vial

1. Remove the plastic cap and disinfect the outer part of the rubber stopper of the vial

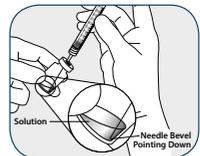


2. Attach the 18 G, 5 micron filter needle supplied in the carton to a 1 ml sterile, Luer-lock syringe



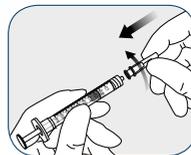
3. Push the filter needle into the centre of the vial stopper until the needle is completely inserted into the vial and the tip touches the bottom or bottom edge of the vial

4. Using aseptic technique withdraw all of the EYLEA vial contents 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



5. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle
6. Remove the filter needle and properly dispose of it.
Note: Filter needle is not to be used for intravitreal injection

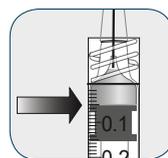
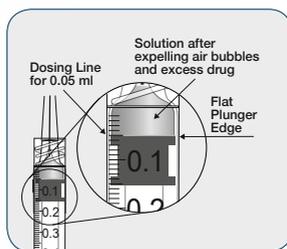
7. Using aseptic technique, firmly twist a 30 G x ½ inch injection needle onto the Luer-lock syringe tip



8. 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



9. Eliminate all bubbles and expel excess medicinal product by slowly depressing the plunger so that the plunger tip aligns with the line that marks 0.05 ml on the syringe



10. The vial is for single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements



INJECTION PROCEDURE

1. Administer topical anaesthesia



2. Instill disinfectant (e.g. 5% povidone iodine solution or equivalent) according to manufacturer's guidance. Eye dilation prior to the injection procedure is **not** necessary



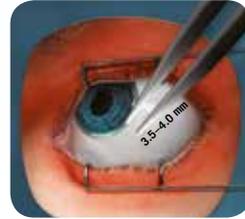
3. Apply disinfectant (e.g. 10% povidone iodine solution or equivalent) to periocular skin, eyelids, eyelid margins and eyelashes, avoiding excessive pressure on eyelids



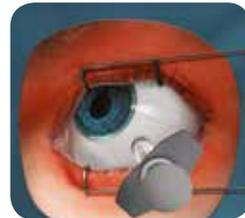
4. Cover with sterile drape and insert sterile lid speculum



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- 5.** Tell your patient to look away from the injection site. Position the eye adequately. At an area 3.5 to 4.0 mm posterior to the limbus, mark an injection site



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- 6.** Insert the injection needle into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. The injection volume of 0.05 ml is then delivered; a different scleral site should be used for subsequent injections



AFTER THE INJECTION

- Evaluate vision immediately after injection (hand movement or finger counting)
- Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, sterile equipment for paracentesis should be available
- Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g., eye pain, redness of the eye, photophobia, blurring of vision) without delay
- Application of antibiotic eye drops after intravitreal injections should be according to local or national clinical guidelines and at the discretion of the treating clinician
- Please inform your patients that they could experience:
 - Bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye (conjunctival haemorrhage)
 - Moving spots in their vision (vitreous floaters)
 - Eye pain

These conditions normally go away a few days after the injection. Please advise your patients to seek medical attention if these conditions do not go away in a few days, or get worse.

ADVERSE REACTIONS

Please inform your patients that they could experience the following adverse reactions:

- Endophthalmitis
- Cataract (traumatic, nuclear, subcapsular, cortical) or lenticular opacities
- Transient increase in intraocular pressure

To allow for early treatment, please also instruct your patients to report without delay any of the following symptoms, suggestive of serious adverse events:

- Increased eye pain
- Worsening redness of the eye
- Vision gets more blurred than usual or inability to see as well as usual
- Increased sensitivity to light
- Sudden appearance of floaters, flashes of light and/or obscured vision

For comprehensive information about adverse reactions, please see section 4.8 of the SmPC.

MANAGEMENT OF INJECTION-RELATED ADVERSE EVENTS

Make sure that, in case of any adverse event that concerns your patient, your patient has immediate access to an ophthalmologist.

Appropriate action and treatment of ALL adverse events, including those associated with the intravitreal injection procedure, should be carried out according to established clinical practice and/or following standardised guidelines.

For this reason, it is important to advise your patients to inform their doctor, pharmacist or nurse if they experience any side effects. This includes any possible side effects not listed in the Package Leaflet. Patients 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, patients can help provide more information on the safety of EYLEA.





Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to Bayer plc.

Tel: 0118 2063500, Fax: 0118 2063703, Email: pvuk@bayer.com