

## **Abridged prescribing information:**

### **Composition:**

EYLEA, 40 mg / mL solution for injection. One milliliter solution for injection contains 40 mg aflibercept. Each vial provides a usable amount to deliver a single dose of 50 microliters containing 2 mg aflibercept.

### **Indications: EYLEA is indicated for the treatment of**

Neovascular (wet) age-related macular degeneration (wet AMD)  
Macular edema secondary to central retinal vein occlusion (CRVO)  
Macular edema secondary to branch retinal vein occlusion (BRVO)  
Diabetic macular edema (DME)  
Myopic choroidal neovascularization (myopic CNV)

### **Dosage & Duration of Treatment**

#### ***Neovascular (wet) age-related macular degeneration (wetAMD)***

The recommended dose for EYLEA is 2 mg (equivalent to 50 microliters). EYLEA treatment is initiated with one injection per month for three consecutive doses, followed by one injection every 2 months. Based on Physician's judgement of visual and /or anatomic outcomes the treatment interval may be maintained at two months or further extended using a treat –and –extend dosing regimen, where injection intervals are gradually increased to maintained stable visual and /or anatomic outcomes. If visual and /or anatomic outcomes deteriorate the treatment interval should be shortened accordingly.

#### ***Macular edema secondary to central retinal vein occlusion (CRVO)***

The recommended dose for EYLEA is 2 mg (equivalent to 50 microliters). After the initial injection, treatment is given monthly until visual and/or anatomic outcomes are stable. Three or more consecutive, monthly injections may be needed. Treatment should be continued, and the interval may be extended based on visual and/or anatomic outcomes.

#### ***Macular edema secondary to branch retinal vein occlusion (BRVO)***

The recommended dose for Eylea is 2 mg (equivalent to 50 microliters). After the initial injection, treatment is given monthly until Visual and/or anatomic outcomes are stable. Three or more consecutive, monthly injections may be needed. Treatment should be continued, and the interval may be extended based on visual and/or anatomic outcomes.

#### ***Diabetic macular edema (DME)***

The recommended dose for EYLEA is 2 mg (equivalent to 50 microliters) administered by intravitreal injection monthly for the first 5 consecutive doses, followed by one injection every 2 months. Based on the physician's judgement of visual and/or anatomic outcomes, the treatment interval may be maintained at 2 months or individualized, such as with a treat-and-extend, dosing regimen, where the treatment intervals are gradually increased to maintain stable visual and/or anatomic outcomes. There are limited data for treatment intervals longer than 4 months. If visual and/or anatomic outcomes deteriorate, the treatment, interval should be shortened accordingly.

#### ***Myopic choroidal neovascularization (myopic CNV)***

The recommended dose for EYLEA is a single intravitreal injection of 2 mg (equivalent to 50 microliters).

### **Contraindications:**

Ocular or periocular infection, Active severe intraocular inflammation, Known hypersensitivity to aflibercept or to any of the excipients.

### **Special warnings and precautions for use:**

**Endophthalmitis:** Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis. Proper aseptic injection techniques must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay and should be managed appropriately

**Increase in intraocular pressure:** Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection, including with EYLEA. Special precautions are needed in patients with poorly controlled glaucoma. In all cases, both the intraocular pressure and the perfusion of the optic nerve head must therefore be monitored and managed appropriately.

### **Pregnancy and Lactation:**

EYLEA should not be used during pregnancy unless the potential benefit outweighs the potential risk to the fetus.

### **Drug Interactions:**

No formal drug interaction studies have been performed with Eylea.

### **Undesirable Effects:**

Following are very common (> 1/10) to common (> 1/100 to <1/10) Conjunctival, hemorrhage, Eye pain, Retinal pigment epithelial tear\*, Detachment of the retinal pigment epithelium, Cataract, Cataract cortical, Cataract nuclear, Cataract subcapsular, Corneal erosion, Corneal abrasion, Intraocular pressure increased, Vision blurred, Vitreous floaters, Vitreous detachment, Injection site pain, Foreign body sensation in eyes, Lacrimation increased, Eyelid edema, Injection site hemorrhage, Punctate keratitis, Conjunctival hyperemia, Ocular hyperemia

### **Presentation:**

Each carton includes a type I glass vial containing a fill volume of 278 microliter solution for injection with an elastomeric rubber stopper, and an 18 G filter needle.

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