HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EYLEA safely and effectively. See full prescribing information for EYLEA.

EYLEA® (aflibercept) Injection, for intravitreal use
Initial U.S. Approval: 2011

RECENT MAJOR CHANGES

Indications and Usage (1.5)	2/2023
Dosage and Administration (2)	2/2023
Dosage and Administration (2.2, 2.4)	8/2022
Warnings and Precautions (5.3)	2/2023

INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:
Neovascular (Wet) Age-Related Macular Degeneration (AMD) (1.1)
Macular Edema Following Retinal Vein Occlusion (RVO) (1.2)
Diabetic Macular Edema (DME) (1.3)
Diabetic Retinopathy (DR) (1.4)
Retinopathy of Prematurity (ROP) (1.5)

DOSAGE AND ADMINISTRATION

Neovascular (Wet) Age-Related Macular Degeneration (AMD)
The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). (2.5)
Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months). (2.5)
Although not as effective as the recommended every 8 week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly. (2.5)

Macular Edema Following Retinal Vein Occlusion (RVO)
The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly). (2.6)

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)
The recommended dose for EYLEA is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months). (2.7, 2.8)
Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months). (2.7, 2.8)

Retinopathy of Prematurity (ROP)
The recommended dose for EYLEA is 0.4 mg (0.01 mL or 10 microliters) administered by intravitreal injection. Treatment may be given bilaterally on the same day. Injections may be repeated in each eye. The treatment interval between doses injected into the same eye should be at least 10 days.(2.9)

DOSAGE FORMS AND STRENGTHS

- Injection: 2 mg/0.05 mL solution in a single-dose pre-filled syringe (3)
- Injection: 2 mg/0.05 mL solution in a single-dose vial (3)

CONTRAINDICATIONS

Ocular or periocular infection (4.1)
Active intraocular inflammation (4.2)
Hypersensitivity (4.3)

WARNINGS AND PRECAUTIONS

Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. (5.1)
Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. (5.2)
In infants with ROP, treatment with EYLEA will necessitate extended periods of ROP monitoring (5.3)
There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. (5.4)

ADVERSE REACTIONS

The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Regeneron at 1-855-395-3248 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 2/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

EYLEA is indicated for the treatment of:

1.1 Neovascular (Wet) Age-Related Macular Degeneration (AMD)

1.2 Macular Edema Following Retinal Vein Occlusion (RVO)

1.3 Diabetic Macular Edema (DME)

1.4 Diabetic Retinopathy (DR)

1.5 Retinopathy of Prematurity (ROP)

2 DOSAGE AND ADMINISTRATION

2.1 Important Injection Instructions

For ophthalmic intravitreal injection. EYLEA must only be administered by a qualified physician.

Pre-filled Syringe: A 30-gauge × ½-inch sterile injection needle is needed but not provided.

Vial: A 5-micron sterile filter needle (19-gauge × 1½-inch), a 1-mL Luer lock syringe and a 30-gauge × ½-inch sterile injection needle are needed.

EYLEA is available packaged as follows:

- Pre-filled Syringe
- Vial Kit with Injection Components (filter needle, syringe, injection needle)

[see How Supplied/Storage and Handling (16)].

2.2 Preparation for Administration - Pre-filled Syringe

The EYLEA pre-filled glass syringe is sterile and for single use only. **Do not** use the EYLEA pre-filled syringe for the treatment of ROP.

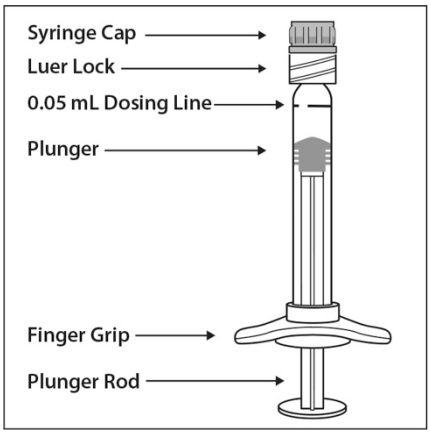
The pre-filled syringe should be inspected visually prior to administration. **Do not** use if particulates, cloudiness, or discoloration are visible, or if the package is open or damaged. The appearance of the syringe cap on the pre-filled syringe may vary (for example, color and design)

Do not use if any part of the pre-filled syringe is damaged or if the syringe cap is detached from the Luer lock.

The intravitreal injection should be performed with a 30-gauge x ½-inch injection needle (not provided).

The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 50 microliters). **The excess volume must be discarded prior to the administration.**

PRE-FILLED SYRINGE DESCRIPTION – Figure 1:



Use aseptic technique to carry out the following steps:

1. PREPARE

When ready to administer EYLEA, open the carton and remove sterilized blister pack. Carefully peel open the sterilized blister pack ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.

2. REMOVE SYRINGE

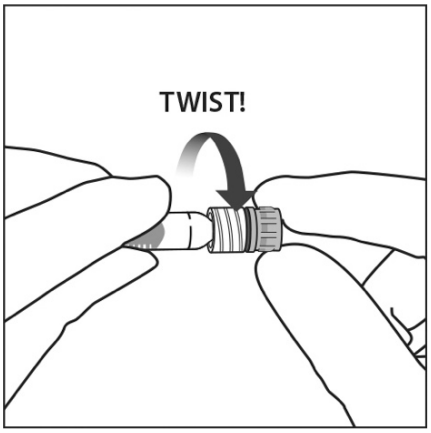
Using aseptic technique, remove the syringe from the sterilized blister pack.

3. TWIST OFF SYRINGE CAP

Twist off (do not snap off) the syringe cap by holding the syringe in one hand and the syringe cap with the thumb and forefinger of the other hand (see Figure 2).

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

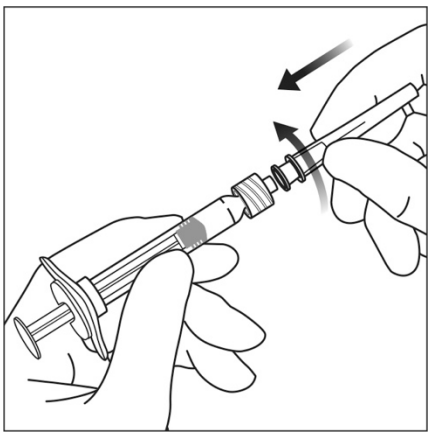
Figure 2:



4. ATTACH NEEDLE

Using aseptic technique, firmly twist a 30-gauge x ½-inch injection needle onto the Luer lock syringe tip (see Figure 3).

Figure 3:

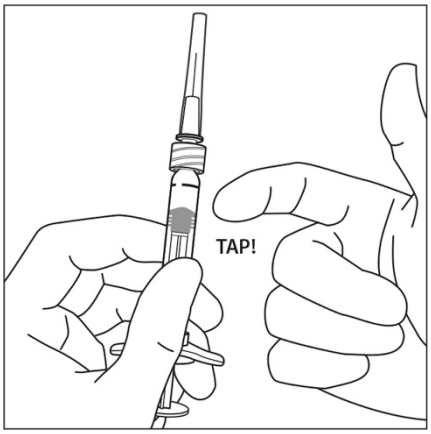


Note: When ready to administer EYLEA, remove the plastic needle shield from the needle.

5. DISLODGE AIR BUBBLES

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 (see Figure 4).

Figure 4:



6. EXPEL AIR AND SET THE DOSE

To eliminate all bubbles and to expel excess drug, slowly depress the plunger rod to align the plunger dome edge (see Figure 5a) with the black dosing line on the syringe (equivalent to 50 microliters) (see Figure 5b).

Figure 5a:

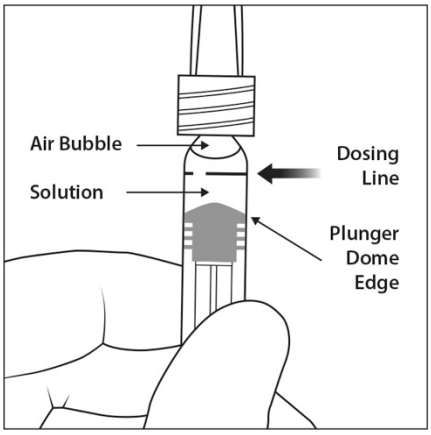
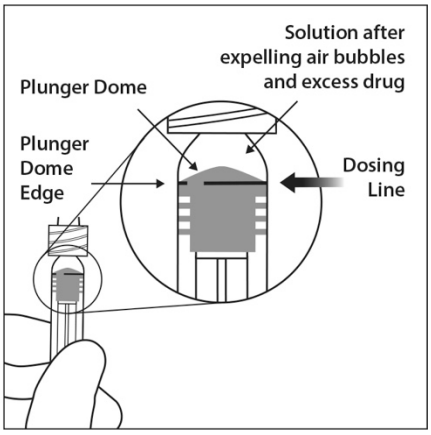


Figure 5b:



7. The pre-filled syringe is for single use only. After injection any unused product must be discarded.

DOCKET ALARM

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