

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)

- 1986

This medicine is dispensed with a doctor's prescription only

Eylea 8 mg

Solution for intravitreal injection

Active ingredient

1 ml of solution contains aflibercept 114.3 mg/ml.

Each pre-filled syringe contains 0.184 ml (21 mg aflibercept).

Injection of a single dose with a volume of 0.07 ml delivers 8 mg aflibercept.

Inactive ingredients and allergens in this medicine: see section 2 "Important information regarding some of the ingredients of the medication" and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to the leaflet, Eylea also has a patient safety information guide. This guide contains important safety information that you need to know and that you should follow before you start and during treatment with Eylea. Carefully read the patient safety information guide and patient information leaflet before using this medicine. Keep the guide in case you need to read it again.

1. What is this medicine intended for?

- Eylea is indicated in adults for the treatment of: wet age-related macular degeneration (wet AMD)
- visual impairment due to diabetic macular oedema (DME)

Therapeutic group: Ophthalmics - antineovascularisation agents

How Eylea works

Wet AMD and visual impairment due to DME 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 DME. Both disorders may impact your vision.

Eylea stops growth of new abnormal blood vessels in the eye. Eylea can help to stabilise and often improve vision.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient aflibercept or to any of the other ingredients in this medicine. For the list of the inactive ingredients, see section 6.
- You have an active or suspected infection in or around the eye.
- You have pain or redness in your eye (severe eye inflammation).

Special warnings about using this medicine**Before using Eylea, tell your doctor if:**

- You have glaucoma – an eye condition caused by high pressure in the eye
- You have a history of seeing flashes of light or dark floating spots and if their size or number suddenly increases
- You have 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 certain 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 formation 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 transient ischemic attack (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.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before you receive this medicine.

Pregnancy

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 no information 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.

Breastfeeding

Based on the very limited information in humans, small amounts of Eylea may pass into breast milk. The effect on breastfed newborns/infants are unknown. Eylea is not recommended during breastfeeding.

Driving and using machines

Injection with Eylea has a minor influence on the ability to drive and use machines due to possible temporary visual disturbances associated either with the injection or the eye examination. Do not drive or use machines until visual function has recovered sufficiently.

Important information regarding some of the ingredients of the medication

Eylea contains polysorbate 20

This medicine contains 0.021 mg of polysorbate 20 in each 0.07 ml dose which is equivalent to 0.3 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use this medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage 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 once every 5 months. Your doctor will decide on the frequency based on the condition of your eye.

Do not exceed the recommended dose.

Method of administration

Your doctor will inject Eylea into your eye (intravitreal injection).

Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor will give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent pain from the injection.

If you missed an injection of Eylea

Make a new appointment with your doctor as soon as possible. Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss and your vision may worsen.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Eylea may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. The side effects of Eylea injection are either from the medicine itself or from the injection procedure and mostly affect the eye.

Serious side effects

Contact your doctor immediately if you experience any of the following effects:

Common side effects - side effects that appear in up to 1 in 10 users:

- Clouding of the eye 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 effects - side effects that appear in up to 1 in 100 users:

- 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, an effect resulting in flashes of light with floaters, sometimes progressing to a loss of vision (retinal detachment or tear)

Additional side effects

Common side effects - side effects that appear in up to 1 in 10 users:

- Allergic reactions
- Moving spots 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 side effects - side effects that appear in up to 1 in 100 users:

- Detachment or tear of one of the layers in the back of the eye, an effect resulting in flashes of light with floaters, sometimes progressing to a loss of vision (retinal pigment epithelial tear/detachment)
- Inflammation of 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/nuclear)
- Damage to the front layer of the eyeball (corneal erosion)
- Blurred vision
- Eye pain at injection site
- A feeling of having a foreign object in the eye
- Increased tear production
- Bleeding at the injection site
- Redness of the eye
- Swelling of the eyelid
- Eye redness (ocular hyperaemia)
- Injection site irritation

Rare side effects - side effects that appear in up to 1 in 1,000 users:

- Swelling of the front layer of the eyeball (corneal oedema)
- Clouding of the lens (lenticular opacity)
- Degeneration of the light-sensitive membrane at the back of the eye (retinal degeneration)
- Eyelid irritation

Not known (frequency cannot be estimated from the available data):
inflammation of the white part of the eye associated with redness and pain (scleritis)

Besides the effects noted 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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C). Do not freeze.
- Keep the pre-filled syringe in its package and in the outer carton in order to protect from light.
- Prior to use, the closed package may be stored at room temperature (below 25°C) for up to 24 hours.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Sucrose, L-arginine monohydrochloride, L-histidine monohydrochloride monohydrate, L-histidine, polysorbate 20, water for injections.

See section 2 "Important information regarding some of the ingredients of the medication"

What the medicine 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.

Each package contains 1 pre-filled syringe.

Registration holder's name and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

Manufacturer's name and address: Bayer AG, Berlin, Germany.

Updated in March 2025

Registration number of the medicine in the Ministry of Health's National Drug

Registry: 177-99-37906-00

Information for the medical staff only:

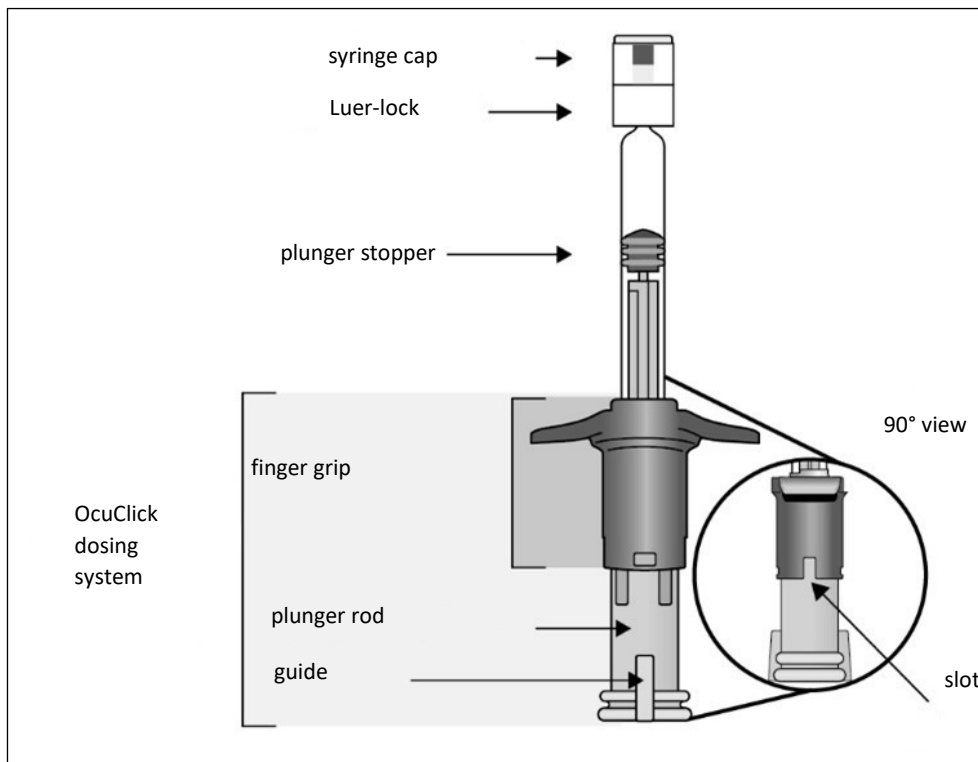
The pre-filled syringe with OcuClick dosing system is for single use in one eye only. Extraction of multiple doses from a single pre-filled syringe with OcuClick dosing system may increase the risk of contamination and subsequent infection.

Do not use if the package or its components are expired, damaged, or have been tampered with. Check the label on the pre-filled syringe with OcuClick dosing system 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 pre-filled syringe.

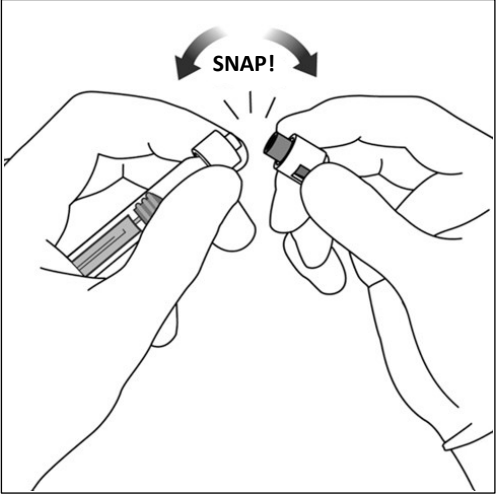
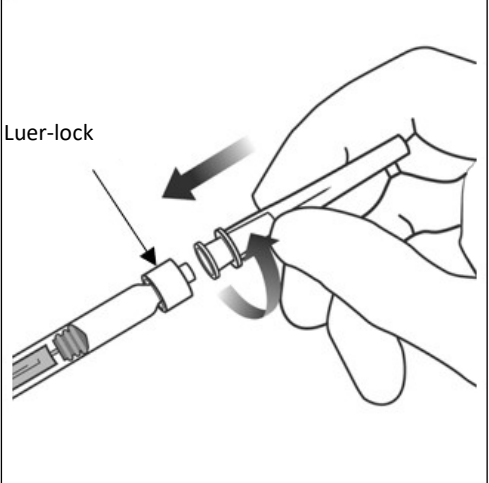
The intravitreal injection should be performed with a 30 G × ½ inch injection needle (not included).

Use of a smaller size needle (higher gauge) than the recommended 30 G × ½ inch injection needle may result in increased injection forces.

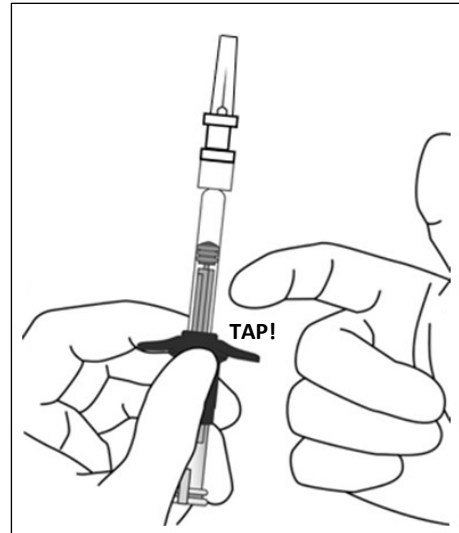
Pre-filled syringe with integrated OcuClick dosing system description



1.	<p>Prepare</p> <p>When ready to administer Eylea 114.3mg/ml, open the carton and remove the sterile blister. Carefully peel open the blister ensuring the sterility of its contents.</p> <p>Keep the syringe in the sterile tray until you are ready to attach the injection needle.</p> <p>Use aseptic technique to carry out steps 2-9.</p>
2.	<p>Remove syringe</p> <p>Remove the syringe from the sterilised blister.</p>
3.	<p>Inspect syringe and solution for injection</p> <p>Do not use the pre-filled syringe if</p> <ul style="list-style-type: none">- particulates, cloudiness, or discolouration are visible- any part of the pre-filled syringe with OcuClick dosing system is damaged or loose- the syringe cap is detached from the Luer-lock.

4.	<p>Snap off syringe cap</p> <p>To snap off (do not twist off) the syringe cap, hold the syringe in one hand and the syringe cap with the thumb and forefinger of the other hand.</p> <p>Note: Do not pull back on the plunger rod.</p>	
5.	<p>Attach needle</p> <p>Firmly twist the 30 G × ½ inch injection needle onto the Luer-lock syringe tip.</p>	
6.	<p>Dislodge air bubbles</p>	

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.

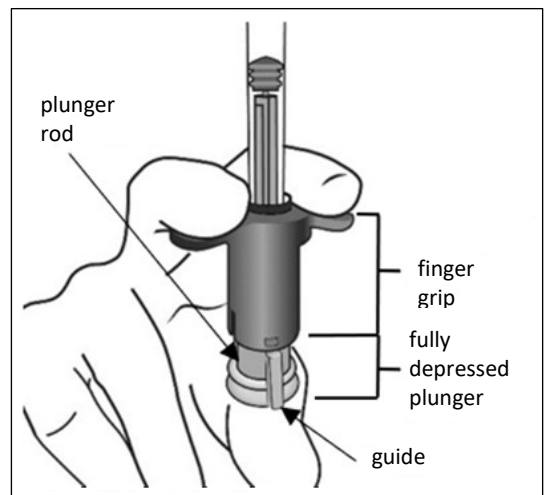
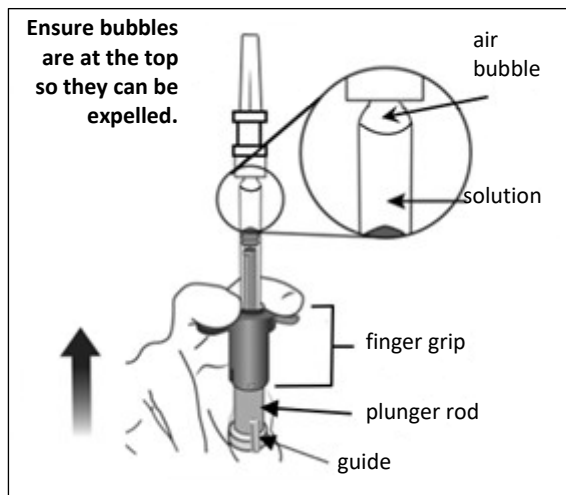


7. Expel air and excess volume to prime

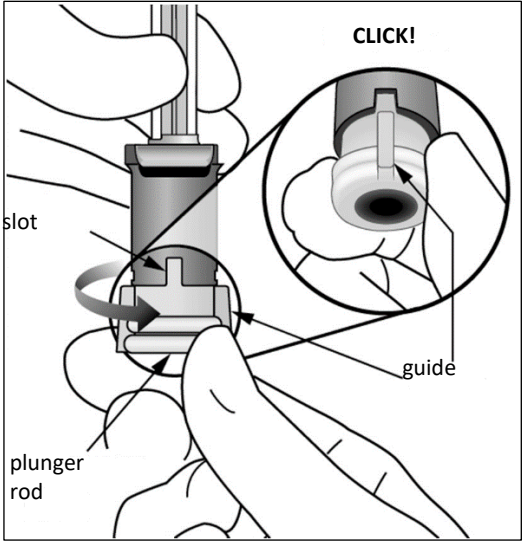
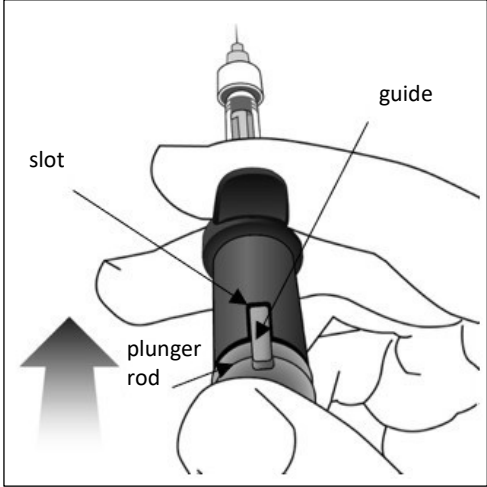
The syringe does not have a dose line because it is designed to set the dose mechanically as explained in the steps below.

Priming and setting the dose must be done using the following steps.

To eliminate all bubbles and to expel excess medicinal product, slowly depress the plunger rod (left picture below) until it stops, i.e. when the guide on the plunger rod reaches the finger grip (right picture below).



8. Set the dose

	<p>Turn the end of the plunger rod 90 degrees clockwise or counter clockwise until the guide of the plunger rod aligns with the slot. You may hear a 'click'.</p> <p>Note: Now the device is ready to dose. Do not push the plunger rod before insertion into the eye.</p>	
<p>9.</p>	<p>Administer the injection</p> <p>Insert the needle into the ocular injection site. Inject the solution by pushing in the plunger rod until it stops, i.e. until the guide is completely within the slot.</p> <p>Do not apply additional pressure once the guide is within the slot. It is normal to see a small amount of residual solution left in the syringe.</p>	
<p>10.</p>	<p>The pre-filled syringe is for single dose administration and single use only.</p> <p>After injection discard the used syringe into a sharps container.</p>	

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.