



אוגוסט 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:
Eylea (PFS)
אייליה (מזרק מוכן לשימוש)
Solution For Intravitreal Injection
Aflibercept 40mg/ml

אנו מבקשים להודיעכם שהעלון לרופא ולצרכן של התכשיר שבנדון עודכן.

ההתוויה המאושרת לתכשיר:

Eylea is indicated for adults for the treatment of

- neovascular (wet) age-related macular degeneration (AMD) (see section 5.1),
- visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) (see section 5.1),
- visual impairment due to diabetic macular oedema (DME) (see section 5.1),
- visual impairment due to myopic choroidal neovascularisation (myopic CNV) (see section 5.1).

בהודעה זו כלולים העידכונים המהותיים בלבד. בפירוט שלהלן מופיע, רק המידע שהתעדכן. תוספת טקסט מסומנת בקו תחתון.

העדכונים בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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One pre-filled syringe contains an extractable volume of at least 0.09 mL 90 microlitres, equivalent to at least 3.6 mg aflibercept. This provides a usable amount to deliver a single dose of 0.05 mL 50 microliters containing 2 mg aflibercept.

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4.2 Posology and method of administration

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The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL solution for injection). The extractable volume of the syringe (90 microliter) ~~is not to be used in total~~ is the amount that can be expelled from the syringe and is not to be used in total. For the Eylea pre-filled syringe, the extractable volume is at least 0.09 mL. The excess volume **must** should be expelled before injecting. the recommended dose (see section 6.6).



Injecting the entire volume of the pre-filled syringe could result in overdose. To expel the air bubbles along with excess medicinal product, slowly depress the plunger to **align the cylindrical base of the plunger dome (not the tip of the dome) with the black dosing line on the syringe** (equivalent to 0.05 mL 50-microliter i.e. 2 mg aflibercept) (see sections 4.9 and 6.6).

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4.4 Special warnings and precautions for use

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The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL). The excess volume must be expelled prior to administration (see sections 4.2 and 6.6).

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6.5 Nature and contents of container

~~90-microliter~~ Solution in pre-filled syringe (type I glass) marked with a black dosing line, with a plunger stopper (elastomeric rubber) and a Luer lock adaptor with a tip cap (elastomeric rubber). Each pre-filled syringe contains an extractable volume of at least 0.09 mL. Pack size of 1 pre-filled syringe.

6.6 Special precautions for disposal and other handling

The pre-filled syringe is for single use in one eye only.
Do not open the sterile pre-filled syringe blister outside the clean administration room.

~~Since the pre-filled syringe contains more volume (90 microlitres) than the recommended dose (50 microlitres), a part of the volume contained in the syringe has to be discarded prior to the administration~~

The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL). The excess volume must be discarded prior to administration.

העלון לצרכן:

אייליה

תמיסה להזרקה תוך עינית

כל מזרק מוכן לשימוש מכיל:

נפח לשאיבה של לפחות 0.09 מ"ל האקוויולנטי לפחות ל- 3.6 מ"ג אפליברספט

(an extractable volume of at least 0.09 mL, equivalent to at least 3.6 mg aflibercept)

אפליברספט 3.6 מ"ג ב- 90 מיקרוליטר (40 מ"ג/מ"ל) (40 מיקרוליטר) (40 מ"ג/מ"ל)
mg/mL)



מידע הרלוונטי לעלון לרופא ולעלון לצרכן:

Instructions for use of pre-filled syringe:

The pre-filled syringe should only be used **for the treatment of a single eye**.

Do not open the sterile pre-filled syringe blister outside the clean administration room.

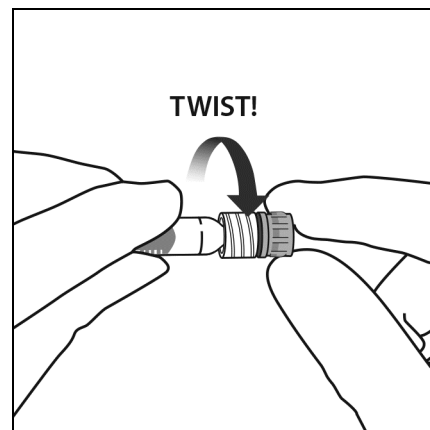
The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL). The excess volume must be discarded prior to administration.

The solution should be inspected visually for any foreign particulate matter and/or discoloration or any variation in physical appearance prior to administration. In the event of either being observed, discard the medicinal product.

The unopened blister may be stored outside the refrigerator below 25° C for up to 24 hours. After opening the blister, proceed under aseptic conditions. For the intravitreal injection, a 30 G x ½ inch injection needle should be used.

Instructions for use of pre-filled syringe:

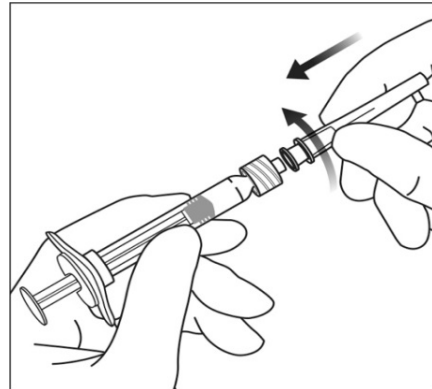
1. When ready to administer Eylea, open the carton and remove the sterilised blister. Carefully peel open the blister ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.
2. Using aseptic technique, remove the syringe from the sterilised blister.
3. To remove the syringe cap, hold the syringe in one hand while using the other hand to grasp the syringe cap with the thumb and fore finger. Please note: You should twist off (do not snap off) the syringe cap.



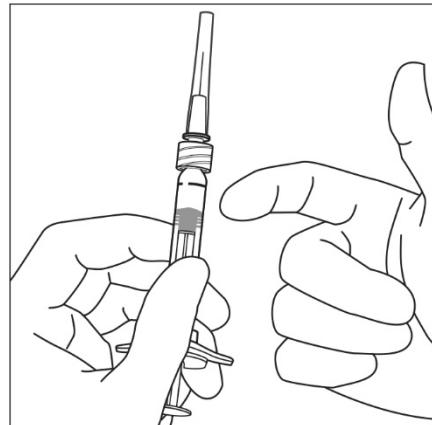
4. To avoid compromising the sterility of the product, do not pull back on the plunger.



5. Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip.



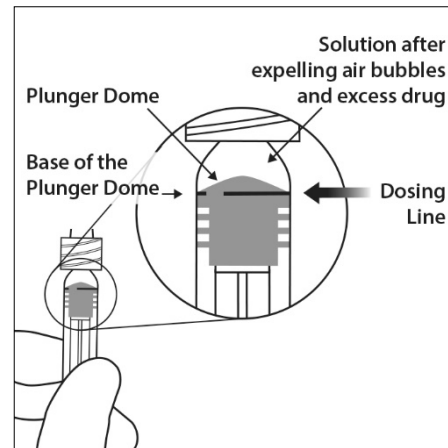
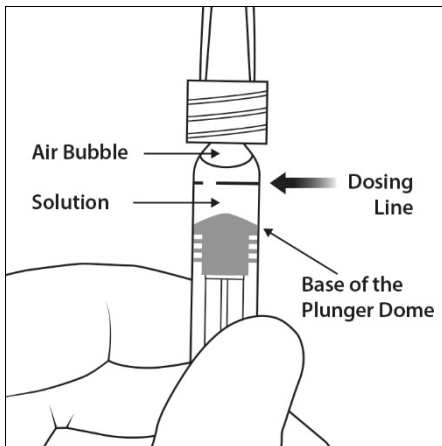
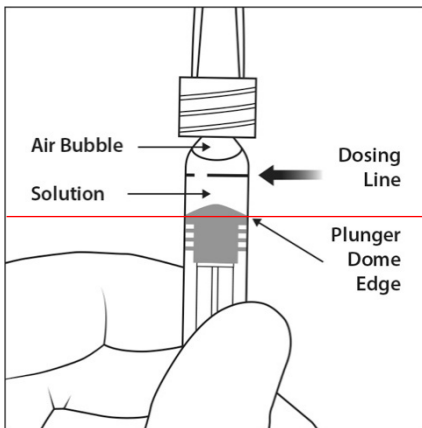
6. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.





7. Eliminate all bubbles and **expel excess medicinal product by slowly depressing the plunger rod to align the cylindrical base of the plunger dome (not the tip of the dome) edge with the black dosing line on the syringe** (equivalent to 50 microliters 0.05 mL i.e. 2 mg aflibercept).

Note: This accurate positioning of the plunger is very important, because incorrect plunger positioning can lead to delivering more or less than the labelled dose.



8. Inject while pressing the plunger carefully and with constant pressure. Do not apply additional pressure once the plunger has reached the bottom of the syringe. Do not administer any residual solution observed in the syringe.

9. The pre-filled syringe is for single use only. Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.



העלון לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#/byDrug>
ניתן לקבלם מודפסים ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700

בברכה,
באייר ישראל