מאי 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:
Eylea
אייליה
Solution For Intravitreal Injection
Aflibercept 40mg/ml

אנו מבקשים להודיעכם שהעלון לרופא והעלון לצרכן של התכשיר שבנדון עודכנו.

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).

לתכשיר נוספת פרזנטציה חדשה – מזרק מוכן מראש
הפרזנטציה החדשה הינה בנוסף לפרזנטציה הקיימת – בקבוקון.
בהודעה זו כלולים העידכונים המהותיים בלבד (המתייחסים להוספת פרזנטציית המזרק) בפירוט שלהלן מופיע, רק המידע שהתעדכן. תוספת טקסט מסומנת בקו תחתון.

העדכונים בעלון לרופא:

1. NAME OF THE MEDICINAL PRODUCT

Eylea 40 mg/ml solution for injection in pre-filled syringe.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains 40 mg aflibercept*.

One pre-filled syringe contains 90 microlitres, equivalent to 3.6 mg aflibercept. This provides a usable amount to deliver a single dose of 50 microlitres containing 2 mg aflibercept.

*Fusion protein consisting of portions of human VEGF (Vascular Endothelial Growth Factor) receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and produced in Chinese hamster ovary (CHO) K1 cells by recombinant DNA technology.

For the full list of excipients, see section 6.1.

4. CLINICAL PARTICULARS

4.2 Posology and method of administration

Eylea is for intravitreal injection only.

Eylea must only be administered by a qualified physician experienced in administering intravitreal injections.

Posology

wet AMD

The recommended dose for Eylea is 2 mg aflibercept, equivalent to 50 microlitres.

Eylea treatment is initiated with one injection per month for three consecutive doses. The treatment interval is then extended to two months.

Based on the 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 increased in 2- or 4-weekly increments to maintain stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly to a minimum of two months during the first 12 months of treatment.

There is no requirement for monitoring between injections.

Based on the physician's judgement the schedule of monitoring visits may be more frequent than the injection visits.

Treatment intervals greater than four months between injections have not been studied (see Section 5.1).

Macular oedema secondary to RVO (branch RVO or central RVO)

The recommended dose for Eylea is 2 mg aflibercept equivalent to 50 microlitres.
After the initial injection, treatment is given monthly. The interval between two doses should not be shorter than one month.

If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.

Monthly treatment continues until maximum visual acuity is achieved and/or there are no signs of disease activity. Three or more consecutive, monthly injections may be needed.

Treatment may then be continued with a treat-and-extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly.

The monitoring and treatment schedule should be determined by the treating physician based on the individual patient's response.

Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography).

Diabetic macular oedema

The recommended dose for Eylea is 2 mg aflibercept equivalent to 50 microlitres.

Eylea treatment is initiated with one injection per month for five consecutive doses, followed by one injection every two months. There is no requirement for monitoring between injections.

After the first 12 months of treatment with Eylea, and based on visual and/or anatomic outcomes, the treatment interval may be extended, such as with a treat-and-extend dosing regimen, where the treatment intervals are gradually increased to maintain stable visual and/or anatomic outcomes; however, there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly.

The schedule for monitoring should therefore be determined by the treating physician and may be more frequent than the schedule of injections.

If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.

Myopic choroidal neovascularisation

The recommended dose for Eylea is a single intravitreal injection of 2 mg aflibercept equivalent to 50 microlitres.

Additional doses may be administered if visual and/or anatomic outcomes indicate that the disease persists. Recurrences should be treated as a new manifestation of the disease.

The schedule for monitoring should be determined by the treating physician.

The interval between two doses should not be shorter than one month.

Special populations

Hepatic and/or renal impairment
No specific studies in patients with hepatic and/or renal impairment have been conducted with Eylea.

Available data do not suggest a need for a dose adjustment with Eylea in these patients (see section 5.2).

Elderly population
No special considerations are needed. There is limited experience in patients older than 75 years with DME.

Paediatric population
The safety and efficacy of Eylea have not been established in children and adolescents. There is no relevant use of Eylea in the paediatric population for the indications of wet AMD, CRVO, BRVO, DME and myopic CNV.

Method of administration

Intravitreal injections must be carried out according to 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. Surgical hand disinfection, sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent) are recommended.

The injection needle should be inserted 3.5-4.0 mm posterior to the limbus 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.

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.

Each pre-filled syringe should only be used for the treatment of a single eye. Extraction of multiple doses from a single pre-filled syringe may increase the risk of contamination and subsequent infection.

The pre-filled syringe contains more than the recommended dose of 2 mg aflibercept. The extractable volume of the syringe (90 microliters) is not to be used in total. The excess volume should be expelled before injecting.

Injecting the entire volume of the pre-filled syringe could result in overdose. To expel the air bubble along with excess medicinal product, slowly depress the plunger to align the cylindrical base of the dome plunger with the black dosing line on the syringe (equivalent to 50 microlitres i.e. 2 mg aflibercept).

After injection any unused product must be discarded.

For handling of the medicinal product before administration, see section 6.6.

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8°C).
Do not freeze.
Store in the original package in order to protect from light.

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.

6.5 Nature and contents of container

90 microlitres of 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). Pack size of 1.

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 blister outside the clean administration room.

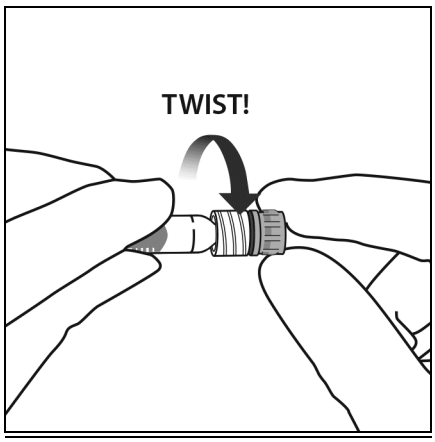
Since the pre-filled syringe contains more volume (90 microlitres) than the recommended dose (50 microlitres), a part of the volume contained in the syringe has to be discarded prior to the administration.

The 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.

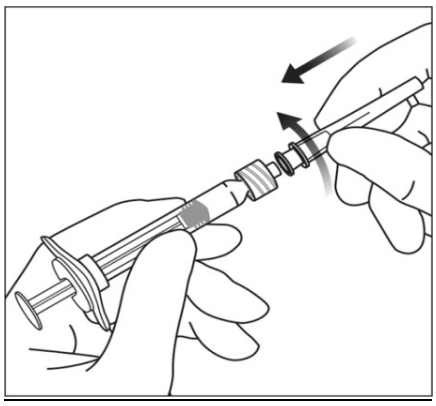
For the intravitreal injection, a 30 G x ½ inch injection needle should be used.

Instructions for use of pre-filled syringe:

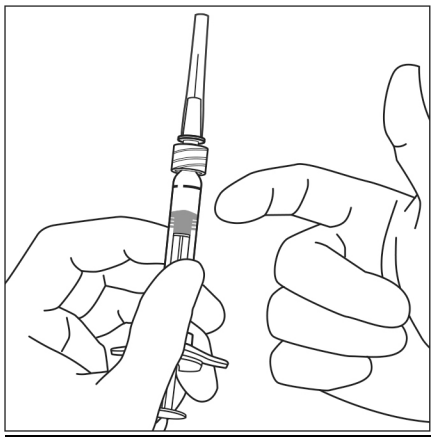
1. When ready to administer Eylea, open the carton and remove the sterilised blister. Carefully peel open the blister ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.
2. Using aseptic technique, remove the syringe from the sterilised blister.
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.



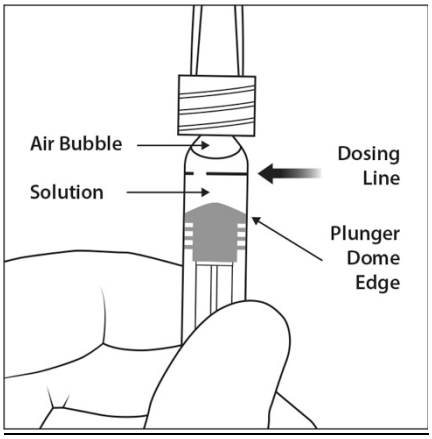
4. To avoid compromising the sterility of the product, do not pull back on the plunger.
5. Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip.



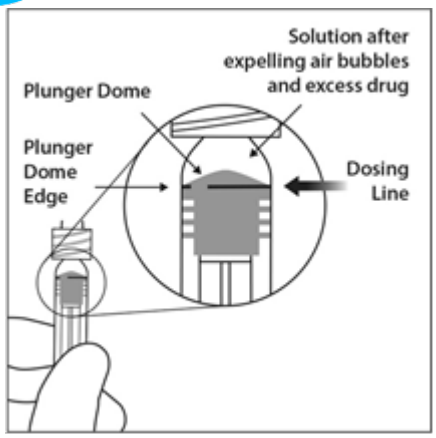
6. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



7. Eliminate all bubbles and expel excess medicinal product by slowly depressing the plunger rod to align the cylindrical base of the plunger dome edge with the black dosing line on the syringe (equivalent to 50 microlitres).



8. 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.



העדכונים בעלון לצרכן:

אייליה
תמיסה להזרקה תוך עינית

כל מזרק מוכן לשימוש מכיל:
אפליברספט 3.6 מ"ג ב- 90 מיקרוליטר (40 מ"ג/מ"ל) Aflibercept 3.6 mg in 90 microliters (40 mg/mL)

. איך לאחסן את התרופה?
- מנע הרעלה! תרופה זו וכל תרופה אחרת יש לשמור במקום סגור מחוץ להישג ידם וטווח ראייתם של ילדים ו/או תינוקות ועל-ידי כך תמנע הרעלה. אל תגרום להקאה ללא הוראה מפורשת מהרופא.
- אין להשתמש בתרופה אחרי תאריך התפוגה (exp. date) המופיע על גבי האריזה. תאריך התפוגה מתייחס ליום האחרון של אותו חודש.
  - יש לאחסן במקרר (2°C עד 8°C). אין להקפיא.
  - לפני השימוש, ניתן לאחסן את העטיפה הסגורה בטמפרטורת החדר (מתחת ל- 25°C) למשך עד 24 שעות.

  יש לשמור את המזרק המוכן לשימוש בעטיפה שלו ובאריזה החיצונית על מנת להגן מפני אור.
- אין להשליך תרופות לביוב או לפח אשפה ביתי. שאל את הרוקח איך להשליך תרופות שאינן בשימוש עוד. אמצעים אלו יסייעו להגן על הסביבה.

6. מידע נוסף
- נוסף על החומר הפעיל התרופה מכילה גם:

Sucrose, sodium chloride, sodium phosphate monobasic monohydrate , Sodium phosphate dibasic heptahydrate , polysorbate 20, water for injection.
- כיצד נראית התרופה ומה תוכן האריזה: אייליה הינו תמיסה להזרקה (זריקה) במזרק מוכן לשימוש (3.6 מ"ג/90 מיקרוליטר). התמיסה הינה חסרת צבע עד צהובה בהירה.
- כל אריזה מכילה 1 מזרק מוכן לשימוש.

המידע שלהלן מיועד לאנשי הצוות הרפואי בלבד:

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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 blister outside the clean administration room.
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.

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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.
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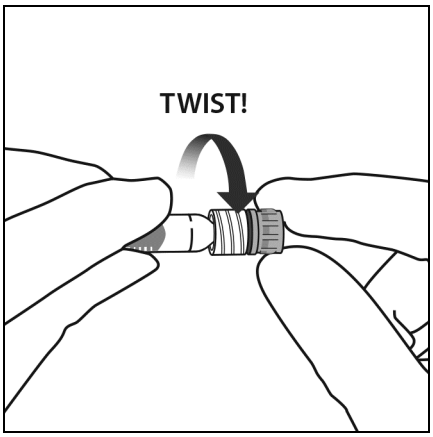
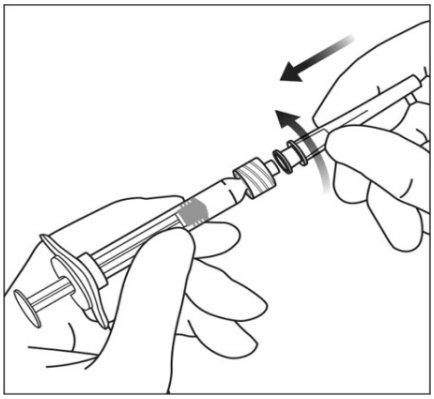
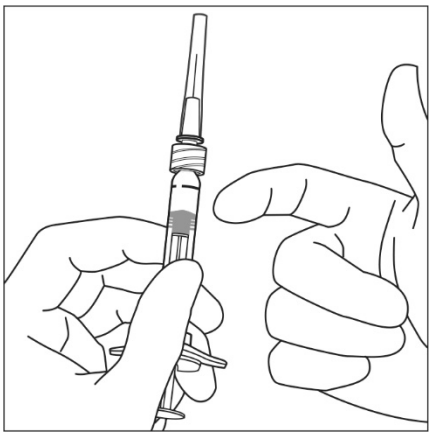


4. To avoid compromising the sterility of the product, do not pull back on the plunger.

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.



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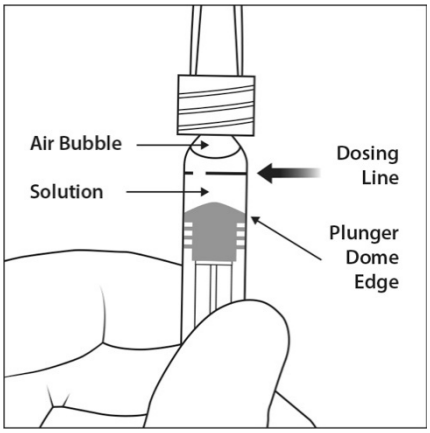

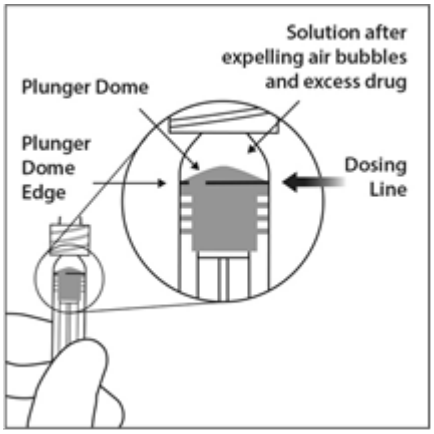

8. The pre-filled syringe is for single use only. Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

העלון לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp
ניתן לקבלם מודפסים ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700

בברכה
באייר ישראל