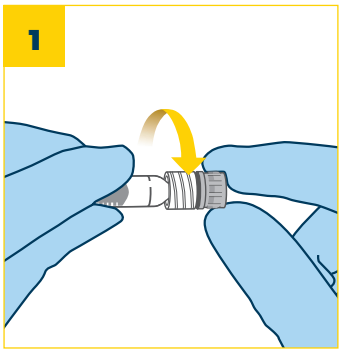
Preparation and handling of the EYLEA® 2mg (aflibercept) pre-filled syringe[1]

The pre-filled syringe is for single use in one eye only. Extraction of multiple doses from the pre-filled syringe may increase risk of contamination and subsequent infection. Prior to administration, visually inspect the solution for injection. Do not use the pre-filled syringe if any foreign particulate matter, discolouration or any variation in physical appearance occurs. Prior to usage, the unopened blister pack of EYLEA 2mg may be stored at room temperature (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. When ready to administer EYLEA 2mg, open the carton and remove the sterilised blister pack. Carefully peel open the blister back ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.

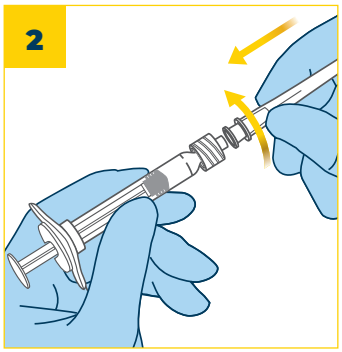
TWIST OFF SYRINGE CAP



Using aseptic technique, remove the syringe from the sterilised blister pack. To remove the syringe cap, hold the syringe in one hand while using your other hand to grasp the syringe cap with the thumb and forefinger.

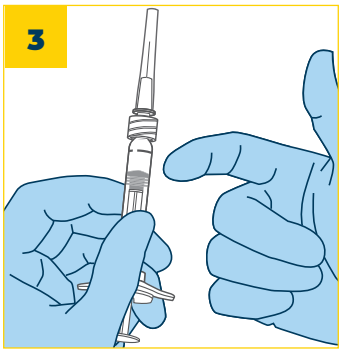
Please note: twist off (do not snap off) the syringe cap. To avoid compromising the sterility of the product, do not pull back on the plunger.

ATTACH SYRINGE TIP



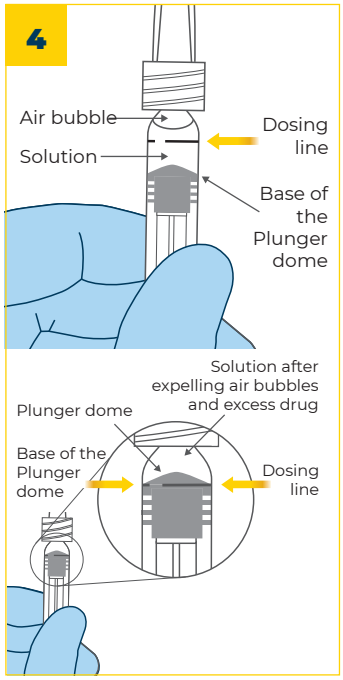
Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip.

CHECK FOR 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.

ELIMINATE ANY BUBBLES



To eliminate all bubbles and to expel the excess drug, slowly depress the plunger to align the base of the plunger dome with the dosing line on the syringe (equivalent to 0.05mL).

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

Reference: EYLEA 2mg SPC as approved by the Israeli MoH.

Indications: Eylea 2mg is indicated for adults for treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DME) and visual impairment due to myopic choroidal neovascularisation (myopic CNV). Contraindications: Hypersensitivity to aflibercept or to any of the excipients. Active or suspected ocular or periocular infection. Active severe intraocular inflammation. Main Warnings and Precautions: Intravitreal injections have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Increases in intraocular pressure (IOP) were seen within 60 min. of intravitreal injection. Special precaution is needed in poorly controlled glaucoma (no injection while IOP is ≥ 30 mmHg). Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors. Safety and efficacy of concurrent use in both eyes have not been systematically studied. Eylea 2mg should not be used in pregnancy unless the potential benefit outweighs the potential risk to the foetus. Women of childbearing potential have to use effective contraception during treatment and for at least 3 months after the last intravitreal injection of aflibercept. In patients presenting with clinical signs of irreversible ischaemic visual function loss, the treatment is not recommended. Eylea 2mg has not been studied in patients with active systemic infections, concurrent eye conditions such as retinal detachment or macular hole, or in diabetic patients with uncontrolled hypertension. This lack of information should be considered when treating such patients. In myopic CNV there is no experience with Eylea 2mg in the treatment of patients who have previously undergone treatment for myopic CNV, and patients with extrafoveal lesions. For full safety profile see MOH approved physician prescribing information.

למידע נוסף אנא עיינו בעלון העדכני כפי שאושר ע"י משרד הבריאות הישראלי.

PP-EYL-IL-0373-1

EYLEA® 2mg
(aflibercept solution for injection)