

## **ABBREVIATED PRESCRIBING INFORMATION:**

### **Aflibercept Injection Solution for Intravitreal use Eylea™ 40mg/ml-**

EYLEA™ SOLUTION FOR INTRAVITREAL INJECTION IN VIAL. Approved name(s) of the active ingredient(s) One ml solution for intravitreal injection contains 40 mg aflibercept. Each single-dose vial provides a usable amount to deliver a single dose of 50 µl containing 2 mg aflibercept. Indication EYLEA™ is indicated for the treatment of (1) neovascular (wet) age-related macular degeneration (wet AMD). (2) diabetic macular edema (DME). Dosage Regimen for wAMD: The recommended dose for Eylea is 2 mg aflibercept (equivalent to 50 microlitres solution for injection). Eylea treatment is initiated with one injection per month (every four weeks) for three consecutive doses, followed by one injection every two months (8 weeks). 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 gradually increased to maintain stable visual and/ or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. 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 injections visits. Treatment intervals greater than 4 months (16 weeks) between injections have not been studied. Dosage Regimen for DME: The recommended dose for EYLEA is 2 mg aflibercept (equivalent to 50 microliters solution for injection) administered by intravitreal injection monthly (once every 4 weeks) for the first 5 consecutive doses, followed by one injection every 2 months (8 weeks). There is no requirement for monitoring between injections. After the first 12 months of treatment with EYLEA and based on the physician's judgement of 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. There are limited data for treatment intervals longer than 4 months. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The schedule for monitoring should be determined by the treating physician and may be more frequent than the schedule of injections. 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. 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 vial should only be used for the treatment of a single eye. Contraindications: Known hypersensitivity to aflibercept or to any of the excipients ocular or periocular infection, active severe intraocular inflammation. Special warnings and precautions for use: Endophthalmitis may occur following intravitreal injections. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. There is a potential risk of immunogenicity and arterial thromboembolic events following intravitreal use of VEGF inhibitors. EYLEA™ 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. Patients may experience temporary visual disturbances after an intravitreal injection and should not drive or use machines until visual function has recovered sufficiently. Undesirable effects Very common: Conjunctival hemorrhage, eye pain. Common: Retinal pigment epithelial tear, detachment of the retinal pigment epithelium, cataract, cataract cortical, cataract nuclear, cataract sub capsular, corneal erosion, corneal abrasion, intraocular pressure increased, vision blurred, vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, lacrimation

increased, eyelid edema, injection site hemorrhage, punctate keratitis, conjunctival hyperemia, ocular hyperemia. For full listing of undesirable effects, please refer to the full product insert. For further prescribing information, please contact Bayer Pharmaceuticals Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: [medicalinfo.india@bayerzyduspharma.com](mailto:medicalinfo.india@bayerzyduspharma.com). Source: Based on CCDS Version 19 dated 16 Mar 2023, cIFU version 01 dated 20 Nov 2020 & CC PI Version 19 dated 16 Mar 2023. PI: EY\_2024\_01 dated 25 July\_2024. Date of revision of API, Dec 2025. For the use of Registered Medical Practitioner or Hospital or Laboratory only