For United Kingdom

Eylea® (aflibercept) 40 mg/mL solution for injection in pre-filled syringe

Prescribing Information
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1 mL solution for injection contains 40 mg aflibercept. Each pre-filled syringe contains extractable volume of at least 0.09 mL, equivalent to at least 3.6 mg aflibercept. **Indications:** Treatment in adults of neovascular (wet) age-related macular degeneration (wAMD), macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DMO) and visual impairment due to myopic choroidal neovascularisation (mCNV). **Posology & method of administration:** Administration by intravitreal injection only, according to medical standards and applicable guidelines by a qualified healthcare professional experienced in administering intravitreal injections. Use 30 G × ½ inch injection needle. Each PFS should only be used for the treatment of a single eye; extraction of multiple doses may increase risk of contamination and infection. The PFS contains more than the recommended dose of 2 mg. The extractable volume of the PFS is not to be used in total. Expel excess volume and bubbles before injecting. Refer to SmPC for full details. Recommended dose is 2 mg aflibercept, equivalent to 0.05 mL. *wAMD* Treatment is initiated with 1 injection per month for 3 consecutive doses. The treatment interval is then extended to 2 months. Based on the physician's judgement of visual and/or anatomic outcomes, treatment interval may be maintained at 2 months or further extended using a treat-and-extend (T&E) 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. 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 4 months or shorter than 4 weeks between injections have not been studied. *RVO (branch RVO or central RVO)* After the initial injection, treatment is given monthly at intervals not shorter than 1 month. Discontinue if no benefit in visual and anatomic outcomes. Treat monthly until maximum visual acuity and/or no signs of disease activity; may need three or more consecutive, monthly injections. Treatment may then be continued with a T&E regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however insufficient data to conclude on treatment interval length. Shorten treatment intervals if visual and/or anatomic outcomes deteriorate. Treating physician should determine monitoring/treatment schedule based on individual patient response. *DMO* Initiate treatment with 1 injection/month for 5 consecutive doses, followed by 1 injection every 2 months. Based on physician's judgement of visual and/or anatomic outcomes, maintain treatment interval at 2 months or individualise, such as with a T&E dosing regimen, usually increasing treatment intervals by 2-week increments to maintain stable visual and/or anatomic outcomes. Limited data for treatment intervals longer than 4 months. Shorten treatment interval if visual and/or anatomic outcomes deteriorate. Treatment intervals shorter than 4 weeks not studied. Monitoring schedule should be determined by treating physician. Discontinue treatment if visual and anatomic outcomes show lack of benefit. *mCNV* Administer a single injection. Additional doses may be administered if visual and/or anatomic outcomes indicate persistent disease. Treat recurrences as a new manifestation of the disease. Schedule for monitoring should be determined by treating physician. Interval between 2 doses should not be shorter than 1 month. **Special populations:** ***Hepatic and/or renal impairment:*** No specific studies conducted. Available data do not suggest need for a dose adjustment. ***Elderly:*** No special considerations are needed. Limited experience in those with DMO over 75 years old. ***Paediatric:*** No data available for wAMD, DMO, RVO or mCNV. **Contraindications:** Hypersensitivity to active substance or any excipient; active or suspected ocular or periocular infection; active severe intraocular inflammation. **Warnings & precautions:** Record name and batch number of administered product for traceability. As with other intravitreal therapies endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract have been reported. Aseptic injection technique essential. Monitor patients during the week following injection to permit early treatment of infection. Patients must report symptoms of endophthalmitis or any of the above-mentioned events without delay. Increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injection; take special precaution in patients

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Bayer plc. Tel.: 0118 2063500, Email: pvuk@bayer.com

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with poorly controlled glaucoma (do not inject if IOP ≥ 30 mmHg). Immediately after injection, monitor and manage IOP and perfusion of optic nerve head. Potential for immunogenicity as with other therapeutic proteins; patients should report signs or symptoms of intraocular inflammation or hypersensitivity e.g. pain, photophobia or redness. Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events reported following intravitreal injection of vascular endothelial growth factor (VEGF) inhibitors. Safety and efficacy of concurrent use in both eyes not systemically studied. No data available on concomitant use of Eylea with other anti-VEGF medicinal products (systemic or ocular). Caution in patients with risk factors for development of retinal pigment epithelial tears including large and/or high pigment epithelial retinal detachment. Withhold treatment in patients with: rhegmatogenous retinal detachment or stage 3 or 4 macular holes or with retinal break (do not resume treatment until break is adequately repaired). Withhold treatment and do not resume before next scheduled treatment if: decrease in best-corrected visual acuity of ≥30 letters compared with last assessment; central foveal subretinal haemorrhage, or haemorrhage ≥50% of total lesion area. Do not treat in the 28 days prior to or following performed or planned intraocular surgery. Do not use Eylea in pregnancy unless the potential benefit outweighs the potential risk to the foetus. Women of childbearing potential must use effective contraception during treatment and for at least 3 months after last intravitreal injection. Aflibercept treatment is not recommended if patients have signs of irreversible ischaemic visual function loss. Populations with limited data: experience limited in DMO due to type I diabetes or patients with HbA1c over 12% or with proliferative diabetic retinopathy. Eylea 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. Consider this lack of information when treating such patients. No experience with Eylea in treatment of non-Asian patients with mCNV, patients who have previously undergone treatment for mCNV and patients with extrafoveal lesions. Eylea contains less than 1 mmol sodium (23 mg) per dosage unit. Contains polysorbate 20; polysorbates may cause allergic reactions. **Interactions:** No available data. **Fertility, pregnancy & lactation:** Not recommended during pregnancy unless potential benefit outweighs potential risk to the foetus. No data in pregnant women. Animal studies have shown embryo-foetal toxicity. Women of childbearing potential must use effective contraception during treatment and for at least 3 months after last injection. Not recommended during breastfeeding. Excretion in human milk: unknown. Male and female fertility impairment seen in animal studies with high systemic exposure but not expected after ocular administration with very low systemic exposure. **Effects on ability to drive and use machines:** Possible temporary visual disturbances. Patients should not drive or use machines if vision inadequate. **Undesirable effects:** *Very common:* Visual acuity reduced, retinal haemorrhage, conjunctival haemorrhage (wAMD phase III studies: increased incidence in patients receiving anti-thrombotic agents), eye pain. *Common:* retinal pigment epithelial tear (observed in wAMD studies only), retinal pigment epithelium detachment, retinal degeneration, vitreous haemorrhage, cataract (nuclear or subcapsular), corneal abrasion or erosion, increased intraocular pressure, blurred vision, vitreous floaters or detachment, injection site pain or haemorrhage, foreign body sensation in eyes, increased lacrimation, eyelid oedema, punctate keratitis, conjunctival or ocular hyperaemia. *Serious: cf. CI/W&P - in addition:* blindness, culture positive and culture negative endophthalmitis, cataract traumatic, transient increased intraocular pressure, vitreous detachment, retinal detachment or tear, hypersensitivity (post-marketing reports of hypersensitivity included rash, pruritus, urticaria, and isolated cases of severe anaphylactic/anaphylactoid reactions), vitreous haemorrhage, cortical cataract, lenticular opacities, corneal epithelium defect/erosion, vitritis, uveitis, iritis, iridocyclitis, anterior chamber flare, scleritis, retinal vasculitis, retinal occlusive vasculitis. Arterial thromboembolic events (ATEs) are adverse events potentially related to systemic VEGF inhibition. Theoretical risk of ATEs including stroke and myocardial infarction, following intravitreal use of VEGF inhibitors. Potential for immunogenicity as with all therapeutic proteins. Consult the SmPC for other side effects. **Overdose:** Monitor intraocular pressure and treat if required. **Incompatibilities:** Do not mix with other medicinal products. **Special Precautions for Storage:** Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package. Unopened syringe blisters may be stored outside the refrigerator below 25°C for up to 24 hours before use. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** £816.00. **MA Number:** PLGB 00010/0676. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.
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