**For United Kingdom**

**Eylea® (aflibercept) 114.3 mg/mL solution for injection in a vial &**
**Eylea® (aflibercept) 114.3 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 114.3 mg aflibercept. *Vial:* Each vial contains 30.1 mg aflibercept in 0.263 mL solution. This provides a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. *Pre-filled syringe (PFS):* Each pre-filled syringe contains 21 mg aflibercept in 0.184 mL solution. This provides a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. **Indication(s):** Treatment in adults of neovascular (wet) age-related macular degeneration (nAMD), and visual impairment due to diabetic macular oedema (DMO). **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 a 30 G × ½ inch injection needle. Each vial or PFS should only be used for the treatment of a single eye; extraction of multiple doses from a vial or from a single PFS with OcuClick dosing system may increase risk of contamination and infection. The 8 mg dose requires use of Eylea 114.3 mg/mL vial or PFS with OcuClick dosing system; check label to ensure correct Eylea strength. The extractable volume of the vial (0.263 mL) or total volume of the PFS (0.184 mL) is not to be used in full. Expel excess volume and bubbles before injecting. Refer to SmPC for full details. ***Adults:*** The recommended dose is 8 mg aflibercept, equivalent to 0.07 mL solution. Posology is the same for nAMD and DMO indications. For nAMD and DMO, treatment is initiated with 1 injection per month for 3 consecutive doses. Injection intervals may then be extended up to every 4 months based on physician's judgement of visual and/or anatomic outcomes. Subsequently, treatment intervals may be further extended up to 6 months, such as with a treat-and-extend (T&E) dosing regimen, while maintaining stable visual and/or anatomic outcomes. For patients who have previously been treated with Eylea 40 mg/mL or other vascular endothelial growth factor (VEGF) inhibiting medicinal products and are switching to Eylea 114.3 mg/mL, the treatment regimen can differ from that used for treatment-naïve patients. Treatment intervals should be determined based on visual and/or anatomic outcomes. In patients with stable visual and anatomic outcomes, previous treatment intervals can be maintained or extended after the first injection of Eylea 114.3 mg/mL, such as with a treat-and-extend dosing regimen. In patients with suboptimal visual and/or anatomic outcomes, treatment with Eylea 114.3 mg/mL may begin with 1 injection per month for up to 3 consecutive doses followed by adjustment of injection interval, such as with a treat-and-extend dosing regimen. If visual and/or anatomic outcomes deteriorate, treatment interval should be shortened according to physician's discretion. Shortest interval between 2 injections is 2 months in maintenance phase. Eylea at monthly doses of 8 mg has not been studied for more than 3 consecutive doses. Frequency of monitoring visits should be based on patient's status and physician's discretion. ***Hepatic and/or renal impairment:*** No specific studies conducted. Available data do not suggest need for a dose adjustment. ***Elderly population:*** Available data do not suggest need for dose adjustment. ***Paediatric population:*** Safety and efficacy of Eylea 114.3 mg/mL in children and adolescents below 18 years have not been established. No relevant use of Eylea 114.3 mg/mL in the paediatric population in nAMD and DMO. **Contraindications:** Hypersensitivity to active substance or any excipient; 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, retinal detachment, retinal tear and traumatic cataract have been reported. Aseptic injection technique essential. Patients must report symptoms of endophthalmitis or any of the above-mentioned events without delay. Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injections, including Eylea; monitor and manage IOP and optic nerve head perfusion.

**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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Take special precautions in patients with poorly controlled glaucoma (do not inject if IOP ≥ 30 mmHg). 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 have been reported following intravitreal injection of VEGF inhibitors. There are limited data on safety in patients with nAMD and DMO and history of stroke, transient ischaemic attacks or myocardial infarction within last 6 months. Exercise caution when treating such patients. Safety and efficacy of concurrent use in both eyes not studied; potential risk of increased systemic exposure and systemic adverse events. Limited data 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: decrease in best-corrected visual acuity of ≥30 letters compared with last assessment; rhegmatogenous retinal detachment or stage 3 or 4 macular holes or with retinal break, subretinal haemorrhage in central fovea or ≥50% of total lesion area. Do not treat in 28 days prior to or following performed or planned intraocular surgery. Populations with limited data: experience limited in diabetic patients with an 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. Contains polysorbate 20; polysorbates may cause allergic reactions. **Interactions:** No available data. **Fertility, pregnancy & lactation:** Do not use in pregnancy unless potential benefit outweighs potential risk to the foetus. Limited data in pregnant women. Animal studies have shown reproductive toxicity. Women of childbearing potential must use effective contraception during treatment and for at least 4 months after last injection. Not recommended during breastfeeding. Aflibercept may be excreted in human milk at low levels. Effect on infant is unknown. No fertility data in humans. Animal studies with high systemic exposure indicate aflibercept can impair male and female fertility. **Effects on ability to drive and use machines:** Possible temporary visual disturbances. Patients should not drive or use machines until their visual function has recovered sufficiently. **Undesirable effects:** *Common:* hypersensitivity, cataract, intraocular pressure increased, vitreous floaters, vitreous detachment, vitreous haemorrhage, retinal haemorrhage, visual acuity reduced, eye pain, conjunctival haemorrhage, punctate keratitis, corneal abrasion. *Serious: cf. CI/W&P:* in addition cataract, retinal haemorrhage, IOP increased, vitreous haemorrhage, cataract subcapsular, cataract nuclear, retinal detachment, retinal tear and scleritis. The following adverse reactions of Eylea 40 mg/mL are also considered expected with Eylea 114.3 mg/mL: abnormal sensation in eye, corneal epithelium defect, anterior chamber flare, endophthalmitis, blindness, traumatic cataract, hypopyon, severe anaphylactic/anaphylactoid reactions. Theoretical risk of arterial thromboembolic events (ATEs) including stroke and myocardial infarction following intravitreal use of VEGF inhibitors. A low incidence rate of ATEs was observed in the aflibercept clinical studies in patients with nAMD and DMO. Across indications, no notable difference between the groups treated with Eylea 114.3 mg/mL and the comparator groups treated with Eylea 40 mg/mL were observed. Consult the SmPC in relation to other adverse reactions. **Overdose:** Monitor intraocular pressure and treat if required. **Incompatibilities:** Do not mix with other medicinal products. **Special Precautions for Storage:** Store in refrigerator (2°C to 8°C). Do not freeze. Keep vial in outer carton and PFS in its blister and in the outer carton to protect from light. Prior to usage, the unopened vial or unopened blister may be stored outside refrigerator below 25°C for up to 24 hours. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** *Single vial + filter needle or PFS pack:* £998.00

**MA Number(s):** PLGB 00010/0754 & PLGB 00010/0758 **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.

**Date of preparation:** June 2025


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