For United Kingdom

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. Each pre-filled syringe (PFS) contains 21 mg aflibercept in 0.184 mL solution, providing a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. **Indications:** Treatment in adults of neovascular (wet) age-related macular degeneration (nAMD), visual impairment due to diabetic macular oedema (DMO) and visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO). **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 PFS should only be used for treatment of a single eye; extraction of multiple doses may increase risk of contamination and infection. Each PFS contains more than the recommended dose. The extractable volume of the PFS is not to be used in full. Expel excess volume and bubbles before injecting. The 8 mg dose requires use of Eylea 114.3 mg/mL PFS with OcuClick dosing system; check label to ensure correct Eylea strength. Refer to SmPC for full details. Recommended dose is 8 mg aflibercept, equivalent to 0.07 mL. Treatment is initiated with 1 injection per month for 3 consecutive doses. *nAMD and DMO* 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. *RVO* Injection intervals may then be extended based on the physician's judgement of visual and/or anatomic outcomes. *All indications* 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-naive 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. Frequency of monitoring visits should be based on patient's status and physician's discretion. If visual and/or anatomic outcomes deteriorate, treatment interval should be shortened according to physician's discretion. Interval between 2 injections should not be shorter than 1 month. If visual and/or anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea 114.3 mg/mL should be discontinued. *nAMD and DMO* Eylea at monthly doses of 8 mg has not been studied for more than 3 consecutive doses in the PULSAR (nAMD) and PHOTON (DMO) studies. Available data support the administration of more than 3 consecutive monthly doses for certain patients, however the data are currently limited. **Special populations:** ***Hepatic and/or renal impairment:*** No specific studies conducted. Available data do not suggest need for a dose adjustment. ***Elderly:*** Available data do not suggest need for dose adjustment. ***Paediatric:*** No relevant paediatric use in nAMD, DMO, RVO. **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. Intravitreal injections have been associated with endophthalmitis, intraocular inflammation, retinal tear and detachment, and traumatic cataract. Aseptic injection technique essential. Instruct patients to report symptoms of any of

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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the above-mentioned events without delay. Monitor patients during the week following injection to permit early treatment of infection. 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. Take special precautions in patients with poorly controlled glaucoma (do not inject if IOP ≥ 30 mmHg). Potential for immunogenicity as with other therapeutic proteins; instruct patients to 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. Limited data on safety in patients with nAMD, DMO or RVO 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 after anti-VEGF for nAMD 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; stage 3 or 4 macular holes; 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: diabetic patients with an HbA1c over 12%; proliferative diabetic retinopathy; active systemic infections; concurrent eye conditions such as retinal detachment or macular hole; 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, IOP 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, endophthalmitis, blindness, scleritis, retinal vasculitis, retinal occlusive vasculitis. 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, 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 Eylea clinical studies. 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 SmPC in relation to other adverse reactions. **Overdose:** Monitor IOP 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 PFS in its blister and in the outer carton to protect from light. Prior to usage, the unopened blister may be stored outside refrigerator below 25°C for up to 24 hours. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** £998.00. **MA Number:** PLGB 00010/0758.

Further information available from: Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.

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