Indication(s): Treatment of neovascular (wet) age-related macular degeneration (AMD), macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema (DMO) in adults and visual impairment due to myopic choroidal neovascularisation (myopic CNV).

Posology & method of administration: For intravitreal injection only. Must be administered according to medical standards and applicable guidelines by a qualified physician experienced in administering intravitreal injections. Each vial should only be used for the treatment of a single eye. The vial contains more than the recommended dose of 2 mg. The extractable volume of the vial (100 microlitres) is not to be used in total. The excess volume should be expelled before injecting. Refer to SmPC for full details.

Adults: The recommended dose is 2 mg aflibercept, equivalent to 50 microlitres. For wAMD treatment is initiated with one injection per month for three consecutive doses, followed by one injection every two months. No requirement for monitoring between injections. After the first 12 months of treatment, and based on 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; however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The schedule for monitoring should therefore be determined by treating physician and may be more frequent than the schedule of injections. For RVO (branch RVO or central RVO), after the initial injection, treatment is given monthly at intervals not shorter than one month. Discontinue if visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment. Treat monthly until maximum visual acuity and/or no signs of disease activity. Three or more consecutive, monthly injections may be needed. Treatment may then be continued with a treat and extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes, however there are insufficient data to conclude on the length of these intervals. Shorten treatment intervals if visual and/or anatomic outcomes deteriorate. The monitoring and treatment schedule should be determined by the treating physician based on the individual patient’s response. For DMO, initiate treatment with one injection/month for 5 consecutive doses, followed by one injection every two months. No requirement for monitoring between injections. After the first 12 months of treatment, and based on 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; however there are insufficient data to conclude on the length of these intervals. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. The schedule for monitoring should therefore be determined by the treating physician and may be more frequent than the schedule of injections. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, treatment should be discontinued. For myopic CNV, a single injection is to be administered. Additional doses may be administered if visual and/or anatomic outcomes indicate that the disease persists. Recurrences should be treated as a new manifestation of the disease. The schedule for monitoring should be determined by the treating physician. The interval between two doses should not be shorter than one month.

Hepatic and/or renal impairment: No specific studies have been conducted. Available data do not suggest a need for a dose adjustment.

Elderly population: No special considerations are needed. Limited experience in those with DMO over 75 years old.

Paediatric population: No data available.

Contraindications: Hypersensitivity to active substance or any excipient; active or suspected ocular or periocular infection; active severe intraocular inflammation.

Warnings & precautions: As with other intravitreal therapies endophthalmitis has been reported. Aseptic injection technique essential. Patients should be monitored during the week following the injection to permit early treatment if an infection occurs. Patients must report any symptoms of endophthalmitis without delay. Increases in intraocular pressure have been seen within 60 minutes of intravitreal injection; special precaution is needed in patients with poorly controlled glaucoma (do not inject while the intraocular pressure is ≥ 30 mmHg). Immediately after injection, monitor intraocular pressure and perfusion of optic nerve head and manage appropriately. There is a potential for immunogenicity as with other therapeutic proteins; patients should report any signs or symptoms of intraocular inflammation e.g pain, photophobia or redness, which may be a clinical sign of hypersensitivity. 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. No data is 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 retinal tears.
and/or high pigment epithelial retinal detachment. Withhold treatment in patients with:
rhegmatogenous retinal detachment or stage 3 or 4 macular holes; with retinal break and do not resume
treatment until the break is adequately repaired. Withhold treatment and do not resume before next
scheduled treatment if there is: decrease in best-corrected visual acuity of $\geq 30$ letters compared with
the last assessment; central foveal subretinal haemorrhage, or haemorrhage $\geq 50\%$, of total lesion area.
Do not treat in the 28 days prior to or following performed or planned intraocular surgery. 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. Populations with limited data: There is limited experience of
treatment with Eylea in patients with ischaemic, chronic RVO. In patients presenting with clinical signs
of irreversible ischaemic visual function loss, aflibercept treatment is not recommended. There is
limited experience in DMO due to type 1 diabetes or 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. This lack of information should be considered when treating such
patients. In myopic CNV there is no experience with Eylea in the treatment of non-Asian patients,
patients who have previously undergone treatment for myopic CNV, and patients with extrafoveal
lesions. **Interactions:** No available data. **Fertility, pregnancy & lactation:** Not recommended during
pregnancy unless potential benefit outweighs potential risk to the foetus. No data available in pregnant
women. Studies in animals have shown embryo-foetal toxicity. Women of childbearing potential have
to use effective contraception during treatment and for at least 3 months after the last injection. Not
recommended during breastfeeding. Excretion in human milk: unknown. Male and female fertility
impairment seen in animal studies with high systemic exposure 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, conjunctival haemorrhage (phase III studies: increased
incidence in patients receiving anti-thrombotic agents), eye pain. **Common:** retinal pigment epithelial
tear, detachment of the retinal pigment epithelium, retinal degeneration, vitreous haemorrhage, cataract
(nuclear or subcapsular), corneal abrasion or erosion, increased intraocular pressure, blurred vision,
vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, increased
lacrimation, eyelid oedema, injection site haemorrhage, punctate keratitis, conjunctival or ocular
hyperaemia. **Serious:** cf. CI/W&P - in addition: blindness, endophthalmitis, cataract traumatic, transient
increased intraocular pressure, vitreous detachment, retinal detachment or tear, hypersensitivity (during
the post-marketing period, reports of hypersensitivity included rash, pruritus, urticaria, and isolated
cases of severe anaphylactic/anaphylactoid reactions), vitreous haemorrhage, cortical cataract,
lucenticular opacities, corneal epithelium defect/erosion, vitritis, uveitis, iritis, iridocyclitis, anterior
chamber flare, arterial thromboembolic events (ATEs) are adverse events potentially related to
systemic VEGF inhibition. There is a theoretical risk of arterial thromboembolic events, including
stroke and myocardial infarction, following intravitreal use of VEGF inhibitors. Consult the SmPC in
relation to 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. Unopened vials may be stored at room temperature (below
25°C) for up to 24 hours before use. **Legal Category:** POM. **Package Quantities & Basic NHS
Costs:** Single vial pack £816.00. **MA Number(s):** EU/1/12/797/002. Further information available
from: Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118
206 3000. **Date of preparation:** September 2017.

Eylea® is a trademark of the Bayer Group

Adverse events should be reported. Reporting forms and information can be found at
[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), Adverse events should also be reported to Bayer plc.
Tel.: 0118 2063500, Fax.: 0118 2063703, Email: pvuk@bayer.com