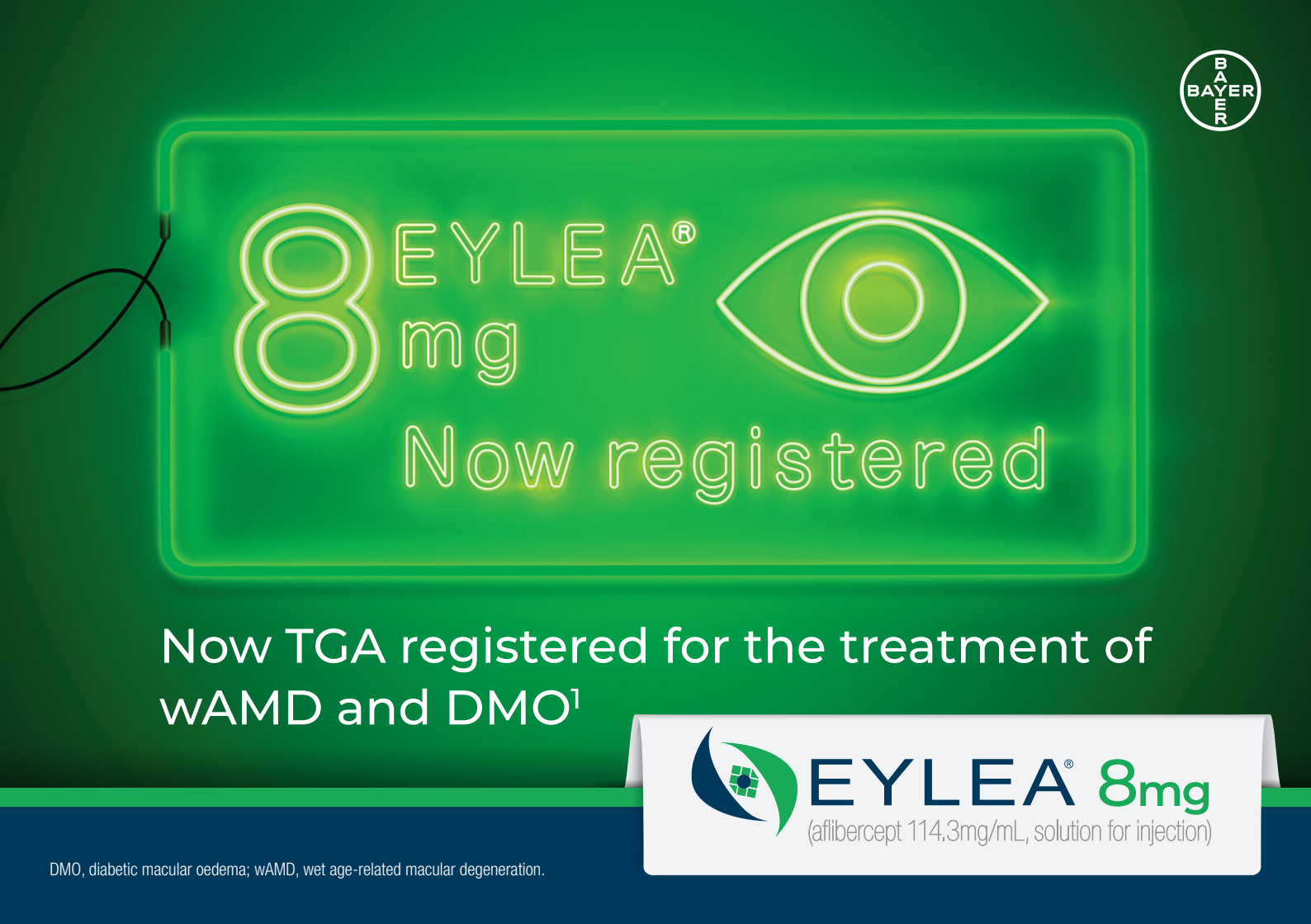
BAYER
8
EYLEA®
mg
Now registered
Now TGA registered for the treatment of wAMD and DMO[1]
EYLEA® 8mg
(aflibercept 114.3mg/mL, solution for injection)
DMO, diabetic macular oedema; wAMD, wet age-related macular degeneration.

PBS Information: EYLEA 8mg is not listed on the PBS. EYLEA 2mg: Authority required for the treatment of wet age-related macular degeneration, diabetic macular oedema, central retinal vein occlusion and branch retinal vein occlusion, myopic choroidal neovascularisation. Refer to PBS schedule for full Authority Required information.

Please review Product Information before prescribing. Full Product Information available upon request from Bayer Australia Ltd or by scanning the QR code.

MINIMUM PRODUCT INFORMATION EYLEA® [aflibercept (rch)] 40 mg/mL (vial for 2mL dosing). EYLEA® [aflibercept (rch)] 40 mg/mL (pre-filled syringe for 2 mg dosing). EYLEA® [aflibercept (rch)] 114.3 mg/mL (vial for 8mg dosing). INDICATIONS: EYLEA 2 mg and 8 mg (aflibercept) is indicated in adults for the treatment of neovascular (wet) age-related macular degeneration (wet AMD); and diabetic macular oedema (DME). EYLEA 2 mg (aflibercept) is indicated in adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO); and visual impairment due to myopic choroidal neovascularisation (myopic CNV). **CONTRAINDICATIONS:** Known hypersensitivity to aflibercept or excipients; ocular or periocular infection; active severe intraocular inflammation. **PRECAUTIONS:** Endophthalmitis, retinal detachment, increase in intraocular pressure; immunogenicity; arterial thromboembolic events; bilateral treatment; risk factors for retinal pigment epithelial tears; treatment should be withheld in case of rhegmatogenous retinal detachment, stage 3 or 4 macular holes, retinal break, decrease in best-corrected visual acuity of ≥ 30 letters, subretinal haemorrhage or intraocular surgery; treatment not recommended in patients with irreversible ischemic visual function loss; population with limited data (diabetic macular oedema due to type 1 diabetes, diabetic patients with HbA1c > 12 %, proliferative diabetic retinopathy, active systemic infections, concurrent eye conditions, uncontrolled hypertension, myopic CNV: no experience in the treatment of non-Asian patients, previous treatment for myopic CNV and extrafoveal lesions); see full PI for effects on fertility, pregnancy, lactation, effects on ability to drive or use machines. **ADVERSE EFFECTS:** Visual acuity reduced, conjunctival haemorrhage, eye pain, retinal pigment epithelial tear, detachment of retinal pigment epithelium, retinal degeneration, vitreous haemorrhage, cataract, cataract cortical, cataract nuclear, cataract subcapsular, corneal erosion, corneal abrasion, intraocular pressure increased, vision blurred, vitreous floaters, vitreous detachment, injection site pain, foreign body sensation in eyes, lacrimation increased, eyelid oedema, injection site haemorrhage, punctate keratitis, conjunctival hyperaemia, ocular hyperaemia. Other: see full PI. Frequency category of adverse effects differ between 2 mg and 8mg dose, see full PI. **DOSAGE AND ADMINISTRATION:** 2 mg or 8 mg aflibercept (equivalent to injection volume of 50 µL and 70 µL respectively). EYLEA is for intravitreal injection only. The interval between doses injected into the same eye should not be shorter than one month. Advice on treatment initiation and maintenance of therapy specific to each patient population is described in the section below. *CRVO, BRVO, myopic CNV: Once optimal visual acuity is achieved and/or there are no signs of disease activity, treatment may then be continued with a treat-and-extend regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes. If disease activity persists or recurs, the treatment interval may be shortened accordingly.* Monitoring should be done at injection visits. The monitoring and treatment schedule should be determined by the treating ophthalmologist based on the individual patient's response. If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, EYLEA should be discontinued. *For wet AMD (2 mg dosing):* Treatment is initiated with one EYLEA 2 mg injection (equivalent to 50 µL) per month for three consecutive months, followed by one injection of EYLEA 2 mg every two months. Treatment interval may be maintained at 2 months or further extended using a treat-and-extend dosing regimen, by increasing injection intervals in 2- or 4-weekly increments. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened to a minimum of 4 weeks. Generally, once optimal visual acuity is achieved and/or there are no signs of disease activity, the treatment interval may be adjusted based on visual and/or anatomic outcomes. The dosing interval can be extended up to every 4 months. *For wet AMD (8 mg dosing):* Treatment is initiated with one EYLEA 8mg injection (equivalent to 70 µL) per month for three consecutive months, followed by one EYLEA 8 mg injection every 8 to 16 weeks based on the ophthalmologist's judgment of visual and/or anatomic outcomes. *For CRVO:* Treatment is initiated with one EYLEA 2 mg injection (equivalent to 50 µL) per month for three consecutive months. After the first three monthly injections, the treatment interval may be adjusted based on visual and/or anatomic outcomes. *For BRVO:* Treatment is initiated with one EYLEA 2 mg injection (equivalent to 50 µL) per month for three consecutive months. After the first three monthly injections, the treatment interval may be adjusted based on visual and/or anatomic outcomes. *For DME (2 mg dosing):* Treatment is initiated with one EYLEA 2 mg injection (equivalent to 50 µL) per month for five consecutive months. Following the initiation period and based on visual and/or anatomical outcomes the treatment interval may be maintained at every 2 months or further extended by intervals of 2 or 4 weekly increments. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. Treatment intervals shorter than 4 weeks or longer than 4 months have not been studied. *For DME (8 mg dosing):* Treatment is initiated with one EYLEA 8mg injection (equivalent to 70 µL) per month for three consecutive months, followed by one EYLEA 8mg injection every 8 to 16 weeks based on the ophthalmologist's judgment of visual and/or anatomic outcomes. *For myopic CNV:* Treatment is initiated with one EYLEA 2 mg injection (equivalent to 50 µL). Additional doses should be administered only if visual and/or anatomic outcomes indicate that the disease persists. Recurrences are treated like a new manifestation of the disease. Based on PI dated 14 June 2024.

Reference: 1. EYLEA® Australian Approved Product Information.