EYLEA® 8mg
(aflibercept 114.3mg/mL, solution for injection)

ADDRESSING UNMET NEEDS

with EYLEA (aflibercept) 8 mg

UK case studies demonstrating early experiences with EYLEA 8 mg in routine clinical practice

DMO, diabetic macular oedema; nAMD, neovascular age-related macular degeneration; SmPC, summary of product characteristics.

This is a promotional material fully funded by Bayer and is intended for UK healthcare professionals only.

EYLEA (aflibercept) 8 mg is indicated in adults for the treatment of nAMD and visual impairment due to DMO.

Please refer to the licensed EYLEA 8 mg SmPC for the full licensed posology and the full summary of the safety profile.

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CHALLENGES

Patients, caregivers and clinics face multiple unmet needs with standard IVT therapies

Frequent injections with standard IVT therapies are associated with **many unmet needs**, including **high treatment burden**, increasing numbers of patients and the high cost of therapy/visits.[1]

Additionally, capacity strain and high clinic workload due to a **lack of durable treatments** may contribute to healthcare costs through **missed appointments** and subsequent **retreatment** and **emergency care**, in addition to **extended staffing hours** and **prolonged waiting times**.[2]

There is a need for durable treatment agents to help address these issues by extending time between injections.[1]

SOLUTIONS

EYLEA 8 mg has the potential to address unmet needs associated with standard IVT therapies

Compared with standard IVT therapies, durable agents could offer patients **long-term vision maintenance** with **fewer injections**.[1]

Fewer injections/visits compared with the current standard of care may also **alleviate workload concerns** for clinics, **increase capacity** to treat a growing patient population, and potentially lead to **cost savings** relative to less durable treatment options.[1,2]

IVT, intravitreal; SmPC, summary of product characteristics.
References can be found at the end of this document.
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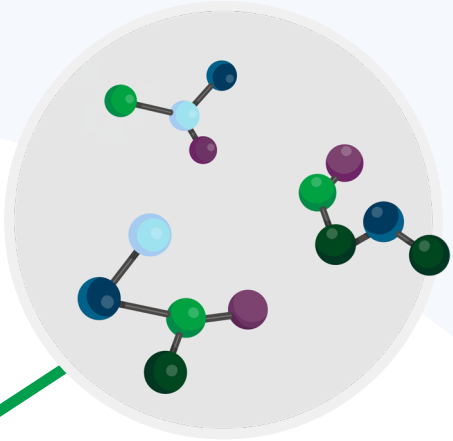
SUSTAINED VEGF SUPPRESSION WITH EYLEA 8 MG

EYLEA 8 mg offers the purpose-designed properties of the aflibercept molecule, at an increased molar dose, to provide sustained VEGF suppression[3]

EYLEA 8 mg presents a different formulation of the specifically designed aflibercept molecule, offering a **four-fold increase in molar dose** and an estimated **34% slower ocular clearance**, compared with the 2 mg formulation.*[3–5]

Owing to its **multi-target binding** and **highest reported binding affinity for VEGF-A_{165}** relative to other licensed anti-VEGF agents, EYLEA 8 mg is ideally suited for **sustained VEGF suppression**.[3–10]



Data from pivotal studies support the efficacy and durability of EYLEA 8 mg

In PULSAR (nAMD) and PHOTON (DMO), EYLEA 8 mg demonstrated **similar efficacy** to EYLEA 2 mg, with **fewer injections** over 96 weeks. The durability of EYLEA 8 mg was demonstrated by **79%** and **89%** of patients randomised to EYLEA 8 mg q16 at baseline maintaining a **last completed treatment interval of ≥q16 at Week 96** in PULSAR and PHOTON, respectively.[11,12] The safety profile of EYLEA 8 mg was **comparable** to that of EYLEA 2 mg over 96 weeks in PULSAR and PHOTON.[11,12]

Durable treatment agents may address unmet needs by extending time between injections compared with standard treatment options

Now with licensed treatment intervals up to 6 months†, EYLEA 8 mg allows you to extend stable patients out to as few as 2 injections per year.[5] Additionally, the UK licensed posology for EYLEA 8 mg for the DMO indication requires **three monthly loading doses in treatment-naïve patients**, compared with five for EYLEA 2 mg.[4,5]

Fewer injections, while **maintaining long-term vision**, may **reduce treatment burden** and **improve treatment adherence** among patients, compared with standard IVT therapies.[1,13,14]

High-durability agents such as EYLEA 8 mg have the potential to address unmet needs that patients, caregivers and clinics face with standard IVT therapies. This material presents early experiences of EYLEA 8 mg use in routine clinical practice in the UK.

*Based on results from a population pharmacokinetic model and simulation.[3] †For patients who are initiating EYLEA treatment, EYLEA is administered with 1 injection per month for 3 consecutive doses. Injection intervals may then be extended up to every 4 months based on the physician's judgement of visual and/or anatomic outcomes. Subsequently, the treatment intervals my be further extended up to 6 months, such as with a T&E dosing regimen, while maintaining stable visual and/or anatomic outcomes.[5]

DMO, diabetic macular oedema; IVT, intravitreal; nAMD, neovascular age-related macular degeneration; q16, every 16 weeks; SmPC, summary of product characteristics; T&E, treat-and-extend; VEGF, vascular endothelial growth factor.

References can be found at the end of this document.

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CASE STUDY 1:

BRISTOL EYE HOSPITAL, UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST

After submitting a BNSSG formulary request in February 2024, the Bristol Eye Hospital received formulary approval for EYLEA 8 mg in April 2024, and the first injection of EYLEA 8 mg was administered on 26 April 2024. From formulary approval through September 2024, there have been a total **681** IVT injections, **17%** of which were bilateral, and **275** patients treated.*

Real-world audit data are available in 40 treatment-naïve eyes with nAMD

Audit data are available from a subset of **40 treatment-naïve eyes** with **nAMD** treated with **three IVT EYLEA 8 mg injections** at **monthly intervals**. Visual and anatomic outcomes were reviewed after the **first** injection and **8 weeks** after the **third** loading dose.

Visual and anatomic outcomes improved with EYLEA 8 mg

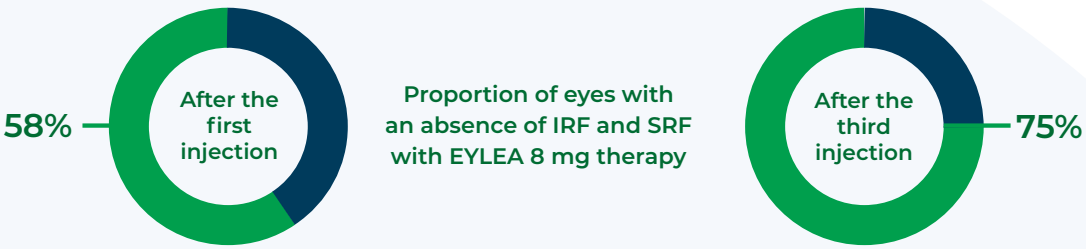
Relative to baseline (**62.0 ± 12.4 ETDRS letters**), visual acuity increased after the first (**65.8 ± 14.2; *P*=0.001**) and third (**68.8 ± 13.6 ETDRS letters; *P*<0.001**) loading dose.

CST decreased from **313.7 ± 95.6 µm** at baseline to **238.9 ± 75.1 µm (*P*<0.001)** after the first and **227.3 ± 43.5 µm (*P*<0.001)** after the third injection.

The drying effect of EYLEA 8 mg was observed from the first injection

A total of **27 (68%)** and **33 (83%)** eyes presented with IRF and SRF, respectively, at baseline. The proportions of eyes with IRF and SRF reduced by **81% (*P*<0.001)** and **61% (*P*<0.001)**, respectively, after the first injection, and by **81% (*P*<0.001)** and **76% (*P*<0.001)**, respectively, after the third injection, compared with baseline.

The majority of eyes were entirely dry with EYLEA 8 mg



EYLEA 8 mg was generally well tolerated by patients*

*As of September 2024, following 681 injections. BNSSG, Bristol, North Somerset and South Gloucestershire; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; IRF, intraretinal fluid; IVT, intravitreal; nAMD, neovascular age-related macular degeneration; SmPC, summary of product characteristics; SRF, subretinal fluid.

Information courtesy of Serena Salvatore.

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CASE STUDY 2:

NEWMEDICA EYE CLINIC – GRIMSBY

Real-world audit data are available in 47 eyes from 38 patients with nAMD:

A total of **25 eyes** from **20 treatment-naïve patients** received **3 monthly injections** with EYLEA 8 mg, as per the UK label; observations were made at **baseline** and after the **first (n=24)** and **third (n=5) loading injections**.

A total of **22 eyes** from **18 treatment-experienced patients** were switched from EYLEA 2 mg (n=16), faricimab (n=5) and ranibizumab (n=1). Observations were made at baseline and after the **first injection (n=22)**.

Visual acuity was maintained with EYLEA 8 mg

Baseline vision (**62.8 ETDRS letters**) was maintained after the first (**64.4 ETDRS letters**) and third (**62.5 ETDRS letters**) injection in treatment-naïve patients.

Relative to baseline (**72 ETDRS letters**), an increase of **5 letters** was observed after the first injection (**77 ETDRS letters**) in treatment-experienced patients.

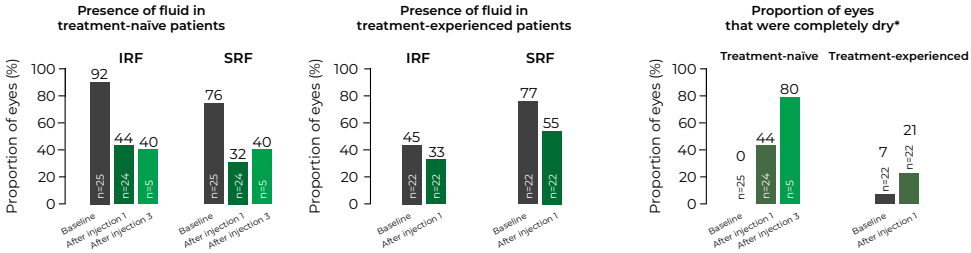
A drying effect was observed after the first injection with EYLEA 8 mg

CRT decreased from **331 µm** at baseline to **280 µm** after one injection and **remained stable at 286 µm** after the **third injection** in treatment-naïve patients.

CRT was similar at baseline (**282 µm**) and following one injection (**275 µm**) in treatment-experienced patients.

The proportion of patients with fluid decreased relative to baseline with EYLEA 8 mg therapy

There was an increase in the proportion of eyes with a complete absence of fluid* relative to baseline with EYLEA 8 mg therapy



The safety profile of EYLEA 8 mg was similar to that shown in published data from PULSAR and PHOTON

No new safety signals observed

No cases of intraocular inflammation reported

> **My overall impressions of EYLEA 8 mg in clinical practice have been good, and largely in line with what I'd anticipate from the PULSAR and PHOTON studies**
>
> Richard Gale, Consultant Ophthalmologist, Newmedica Eye Clinic – Grimsby; excerpt from Bayer's Macular Minute† podcast

*Defined as the absence of IRF and SRF. †The Macular Minute podcast is a promotional podcast series owned, organised and fully funded by Bayer for UK healthcare professionals. CRT, central retinal thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; IRF, intraretinal fluid; nAMD, neovascular age-related macular degeneration; SmPC, summary of product characteristics; SRF, subretinal fluid.

Information courtesy of Richard Gale.

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CASE STUDY 3:

WESTERN EYE HOSPITAL, IMPERIAL COLLEGE HEALTHCARE NHS TRUST

Between **March** and **August 2024**, **52 eyes** from **51 patients** with nAMD were treated with EYLEA 8 mg at the Western Eye Hospital; efficacy and safety outcomes were analysed retrospectively.

Treatment-naïve (17 eyes)

Treatment-experienced (35 eyes)

All treatment-naïve eyes received at least **two** injections, and **15 eyes** received **three** injections.

All treatment-experienced eyes received at least **one** injection; **one eye** received **two**, and **34 eyes** received **three** injections.

Treatment-experienced eyes received an average of 25 prior injections; **EYLEA 2 mg was the most common switch agent (n=16)**, followed by faricimab (n=10).

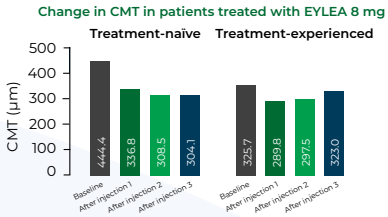
Patients maintained vision with EYLEA 8 mg

In treatment-naïve eyes, **vision** improved by **10 ETDRS letters** after the third injection, from a baseline of **60 ETDRS letters**.

In treatment-experienced eyes, **vision** was maintained at **67 ETDRS letters** after the third injection, from a baseline of **65 ETDRS letters**.

Patients showed evidence of rapid drying with EYLEA 8 mg

CMT decreased from **444.4 µm** at baseline to **304.1 µm** after the third injection in treatment-naïve eyes and remained stable in treatment-experienced eyes (**325.7 µm** at baseline vs. **323.0 µm** after injection three).



A total of **14** and **16** treatment-naïve eyes presented with **IRF** and **SRF**, respectively, at baseline; after the third injection, **IRF** was observed in **four eyes** and **two eyes** presented with **SRF**.

IRF and **SRF** were present in **17** and **24** of treatment-experienced eyes, respectively, at baseline, and in **6 eyes** (**IRF**) and **9 eyes** (**SRF**) after the third injection.

EYLEA 8 mg was generally well tolerated by patients

1 **One case** of retinal pigment epithelium tear in a treatment-naïve eye

No clinically relevant increases in IOP observed

Most patients demonstrated a dry macula after just one injection of EYLEA 8 mg, leading authors to suggest that interval extension could be expected after the loading phase.

CMT, central macular thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; IOP, intraocular pressure; IRF, intraretinal fluid; nAMD, neovascular age-related macular degeneration; SmPC, summary of product characteristics; SRF, subretinal fluid.

Information courtesy of Aseel Hamoud Bedan.

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EYLEA SAFETY PROFILE

EYLEA (aflibercept 2 mg) safety profile summary:[4]

- In the eight EYLEA 2 mg Phase III studies, the safety population comprised a total of 3,102 patients, of whom 2,501 patients were treated with the recommended dose of 2 mg.
- Serious ocular adverse reactions in the study eye related to the injection procedure have occurred in less than 1 in 1,900 intravitreal injections with EYLEA 2 mg and included blindness, endophthalmitis, retinal detachment, cataract traumatic, cataract, vitreous haemorrhage, vitreous detachment and IOP increased.
- The most frequently observed adverse reactions (in at least 5% of patients treated with EYLEA 2 mg) were conjunctival haemorrhage (25%), retinal haemorrhage (11%), VA reduced (11%), eye pain (10%), cataract (8%), IOP increased (8%), vitreous detachment (7%) and vitreous floaters (7%).

EYLEA (aflibercept 8 mg) safety profile summary:[5]

- A total of 1,217 patients treated with EYLEA 8 mg up to 96 weeks constituted the safety population in three clinical Phase II/III studies (CANDELA, PULSAR, PHOTON).
- Serious adverse reactions were cataract (8.2%), retinal haemorrhage (3.6%), intraocular pressure increased (2.8%), vitreous haemorrhage (1.2%), cataract subcapsular (0.9%), cataract nuclear (0.6%), retinal detachment (0.6%), and retinal tear (0.5%).
- The most frequently observed adverse reactions in patients treated with EYLEA 8 mg were cataract (8.2%), visual acuity reduced (4.4%), vitreous floaters (4.0%), conjunctival haemorrhage (3.8%), vitreous detachment (3.7%), retinal haemorrhage (3.6%), intraocular pressure increased (2.8%) and eye pain (2.0%).
- The safety profile observed in the three clinical studies was similar in patients treated with EYLEA 8 mg (N=1,217) and EYLEA 2 mg (N=556), and in patients with nAMD and DMO.

DMO, diabetic macular oedema; IOP, intraocular pressure; nAMD, neovascular age-related macular degeneration; VA, visual acuity.
SmPC, summary of product characteristics.

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Prescribing Information and adverse event reporting information for EYLEA (aflibercept) is available via the QR code below.

For direct access to this prescribing information, please ensure your device's browser settings have automatic PDF download enabled.