SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EYLEA Solution for Injection
Aflibercept
Contains sugar (sucrose)

Read all of this leaflet carefully before you start treatment with EYLEA injection

- Keep this leaflet. You may need to read it again.
- This leaflet will provide information about the benefits and risks of using EYLEA. It will also advise you on how you will be given EYLEA properly and when to tell your doctor about health-related conditions. If you have further questions, please ask your doctor, professional health care provider, or your pharmacist.
- EYLEA has been prescribed for you personally.

What is in this leaflet

1. What EYLEA is and what it is used for

EYLEA is a solution which is injected into the eye to treat eye conditions called

- Neovascular (wet) age-related macular degeneration, commonly referred to as wet AMD
- Macular oedema following central retinal vein occlusion (CRVO)
- Macular oedema secondary to branch retinal vein occlusion (BRVO)
- Diabetic macular oedema (DME)
- Myopic choroidal neovascularization (myopic CNV).

Aflibercept, the active substance in EYLEA, blocks the activity of a group of factors (known as VEGF-A and PIGF) which, in excess, trigger the abnormal formation of new blood vessels in the eye.

EYLEA has been shown to stop the growth of new abnormal blood vessels in the eye and reduce the amount of fluid and blood leaked into the retina. EYLEA can help to stabilise, and in many cases, improve the vision loss related to wet AMD, CRVO, BRVO, DME and myopic CNV.

2. What you need to know before you are given EYLEA

You will NOT be given EYLEA if you:

- Are allergic (hypersensitive) to aflibercept or any of the other ingredients of EYLEA

- Have severe inflammation of the eye (indicated by pain or redness)
- Have an infection in or around the eye (ocular or periocular infection)
- Are pregnant or are breastfeeding your baby.

Warnings and precautions
Take special care with EYLEA.

- Injection with EYLEA may trigger an increase in eye pressure (intraocular pressure), in some patients, within 60 minutes of the injection. Your doctor may monitor this after each injection. If you have glaucoma, please tell your doctor.
- Injections into the eye, including those with EYLEA, have been associated with an infection of the eye (endophthalmitis). Such an infection may be associated with eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, and increased sensitivity to light. Please contact your doctor immediately if you develop any such signs or symptoms, because it is important to have any symptoms diagnosed and treated as soon as possible.
- Patients with kidney and/or liver malfunction:

Available data do not suggest a need for a dose adjustment with EYLEA if you suffer from hepatic and/or renal impairment (liver and/or kidney problems).

Pregnancy and Breastfeeding
EYLEA should not be given to women who are pregnant. If you are pregnant or planning to become pregnant, discuss this with your doctor before treatment with EYLEA. Women of childbearing potential should use effective contraception during treatment and for at least 3 months after the last intravitreal injection of EYLEA.
You should not breastfeed your baby if you are being treated with EYLEA. Ask your doctor for advice before starting EYLEA treatment.

Other medicines with EYLEA
If you are using or have used recently any other medicines, including complementary or traditional medicines, the use of EYLEA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Driving or using machines
After your injection with EYLEA you may experience some visual disturbances.
Do not drive or use machinery as long as these last.

Important information about some of the ingredients of EYLEA:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before being given EYLEA.

3. How you are given EYLEA

EYLEA is intended for injection into the eye. It must only be given by a doctor experienced in eye injections.
You will not be expected to give yourself EYLEA. It will be given to you by a person who is qualified to do so. EYLEA will be injected under aseptic (clean and sterile) conditions. Before the injection your doctor will use disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

- In neovascular (wet) age-related macular degeneration (wet AMD) EYLEA will be given once a month (every 4 weeks) for the first 3 months (12 weeks) followed by one injection every 2 months (8 weeks) thereafter.
- If you are a patient with macular edema secondary to central retinal vein occlusion you will be treated with EYLEA once a month (every 4 weeks) and assessed monthly (every 4 weeks) until your doctor considers your condition has been stable. Three or more monthly (every 4 weeks) injections may be needed. The interval between two injections should not be shorter than one month (4 weeks).
- After this initial monthly (every 4 weeks) treatment period, treatment should be continued and the interval may be extended based on your doctor's judgment of your condition.
- If you are a patient with macular oedema secondary to branch retinal vein occlusion you will be treated with EYLEA once a month (every 4 weeks) and assessed monthly (every 4 weeks) until your doctor considers your condition has been stable. Three or more monthly (every 4 weeks) injections may be needed. The interval between two injections should not be shorter than one month (4weeks). After this initial monthly (every 4 weeks) treatment period, treatment should be continued and the interval may be extended based on your doctor's judgment of your condition.
- If you are a patient with diabetic macular edema you will be treated with EYLEA once a month (every 4 weeks) for the first 5 consecutive doses, followed by one injection every 2 months (8 weeks) thereafter.
- If you are a patient with myopic choroidal neovascularization you will be treated with one single injection of EYLEA at the beginning of your therapy. You will receive additional injections only if during examination your doctor finds that your disease is still persistent.

If a dose of EYLEA is missed
Make a new appointment for an examination and injection.

Stopping treatment with EYLEA
Your doctor will determine when to stop treatment with EYLEA.
If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

EYLEA can cause side effects.
Not all side effects reported for EYLEA are included in this leaflet. Should your general health worsen or if you experience any untoward effects after you are given EYLEA, please consult your doctor, pharmacist or other healthcare professional for advice.

With administration of EYLEA, there may be some side effects due to the injection procedure. Some of these may be serious and include infection or inflammation inside the eye (endophthalmitis), decreased sharpness of vision (retinal detachment, clouding of the lens due to injury (traumatic cataract), clouding of the lens due to other reasons (cataract), detachment of the gel-like substance inside the eye from the retina (vitreous detachment) and increase of pressure inside the eye (increased intraocular pressure).

The following is a list of the most frequent side effects:

<u>Frequent side effects</u>
- increase in eye pressure (intraocular pressure increased)
- moving spots in vision (vitreous floaters)

- detachment of the vitreous (the gel-like substance inside the eye) from the retina (vitreous detachment)
- decreased sharpness of vision (retinal pigment epithelial tear*, detachment of the retinal pigment epithelium)
- certain forms of clouding of the lens (cataract, cortical cataract, nuclear cataract, subcapsular cataract)
- damage to the front layer of the eyeball (corneal erosion, corneal abrasion, punctate keratitis)
- blurred vision
- injection site pain
- a feeling of having something in the eye (foreign body sensation in eyes)
- increased tear production (increased lacrimation)
- swelling of the eyelid (eyelid oedema)
- bleeding at the injection site (injection site haemorrhage)
- redness of the eye (conjunctival hyperaemia, ocular hyperaemia)
- deterioration of eyesight.

*) Conditions known to be associated with wet AMD; observed in wet AMD patients only.

Less frequent side effects

- detachment or tear of one of the layers in the back of the eye
- bleeding in the eye (vitreous haemorrhage)
- infection or inflammation inside the eye (endophthalmitis)
- allergic reactions (hypersensitivity)
- inflammation in the iris of the eye (iritis)
- inflammation of certain parts of the eye (uveitis, iridocyclitis, anterior chamber flare)
- a certain form of clouding of the lens (lenticular opacities)
- damage of the front layer of the eyeball (corneal epithelium defect)
- swelling of the front layer of the eyeball (corneal oedema)
- clouding of the lens due to injury (cataract traumatic)
- inflammation of a certain part of the eye (vitritis)
- pus in the eye (hypopyon)
- bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye (conjunctival haemorrhage)
- eye pain
- blindness.

There is potential risk of arterial thromboembolic (blood clotting) events such as heart attacks or stroke following injection of EYLEA into the eye.
There is a possibility for an immune reaction (formation of antibodies) with EYLEA.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects
If you get side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EYLEA.

5. How to store EYLEA

Keep all medicines out of the reach and sight of children.
Store in a refrigerator (2 °C to 8 °C). Do not freeze. Any unused or excess solution should be discarded in accordance with local requirements.
Prior to usage, the unopened prefilled syringe/vial may be stored at room temperature (25 °C) for up to 24 hours. Keep the prefilled syringe/vial in its outer carton in order to protect from light.

6. Contents of the pack and other information

What EYLEA contains:
Active substance: The active substance is aflibercept.
The other ingredients are: Polysorbate 20, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium chloride, sucrose, water for injection.
Contains sugar: sucrose.

What EYLEA looks like and contents of the pack
EYLEA is a sterile, clear, colourless to pale yellow solution for injection which has no visible particulate matter.

For prefilled syringes
Each carton includes a sealed blister pack with a sterile 1 ml colourless pre-filled type I glass syringe, containing an extractable volume of 90 microlitre solution for injection, sealed with bromobutyl gray fluoropolymer elastomeric plunger stopper siliconised with silicone oil and a tamper-evident bromobutyl gray elastomeric tip cap that is part of a closure system with Luer lock adaptor. The syringe has a pre-attached plunger rod and a finger plate.

For Vials:
Each carton includes a type I; 2 ml colourless glass vial containing an extractable volume of 100 microlitre solution for injection with butyl gray fluoropolymer coated elastomeric rubber stopper with an aluminium crimp seal with a coloured polypropylene button , and an 18 G filter needle.

Holder of Certificate of Registration
Bayer (Pty) Ltd
27 Wrench Road, Isando,
1609
Reg. No.: 1968/011192/07

This leaflet was last revised in
16 October 2023

Registration number:
A 46/15.4/0841