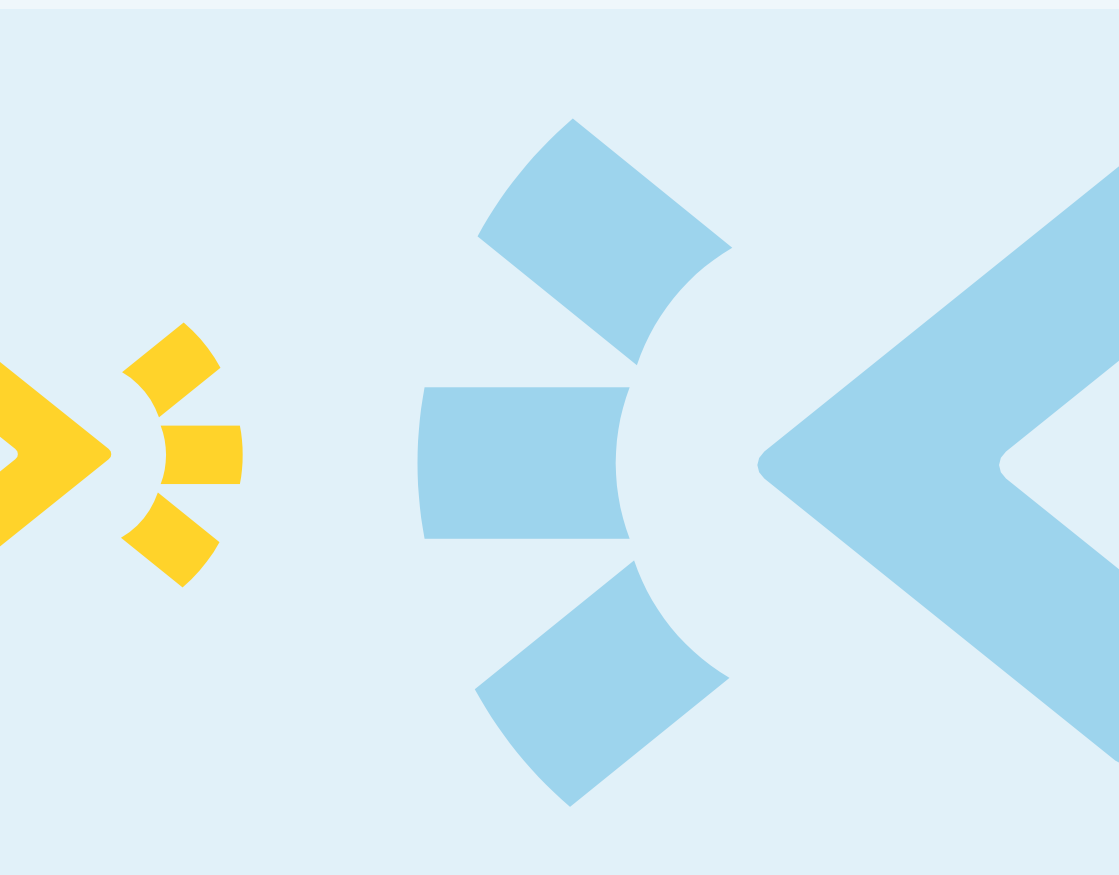


Retinopathy of prematurity (ROP) and EYLEA® (aflibercept)

Information for parents and caregivers



This booklet has been produced by Bayer plc and is intended for parents/caregivers of babies born prematurely who have been prescribed EYLEA (aflibercept) for the treatment of retinopathy of prematurity (ROP).

Your baby and ROP

This booklet has been written for parents and caregivers of babies who have been diagnosed with an eye condition called retinopathy of prematurity or ROP.

Your baby's eye doctor (also known as an ophthalmologist) has recommended a medicine for your baby called EYLEA (afibercept). Within this booklet you will find information about your baby's condition and treatment, including what ROP is, how EYLEA works, what to expect and where to get further advice and support.

We hope you will find this helpful. After reading this booklet, if you have any concerns about your baby's treatment with EYLEA, please speak to your baby's eye doctor.

Help and advice



Once your baby is diagnosed with ROP, it is natural to have many questions. We have included space at the back of this booklet for you to make notes or write down any questions you may have for your baby's eye doctor at your next appointment.



In addition to this booklet, you can also find specific information about EYLEA in the Patient Information Leaflet, which will be provided to you by your baby's eye doctor after the procedure or can be accessed via the QR code provided later on in this booklet.



You may find it helpful to keep a record of the contact details of your baby's eye doctor here so that you can refer to them if needed.

**My baby's
eye doctor's
name:**

**Email
Address:**

**Phone
Number:**

What is retinopathy of prematurity (ROP)?

Retinopathy of prematurity (often shortened to ROP) is an eye condition that affects babies who are born earlier than their expected date of delivery (also called premature, preterm babies or premies).

In babies with ROP, the blood vessels in the back of the eye (retina) do not develop completely.¹ A special growth factor called Vascular Endothelial Growth Factor (VEGF), which is involved in the development of blood vessels in the eye, plays a key role in ROP.²

In most babies, ROP is mild and gets better by itself. However, if severe ROP develops and is left untreated, this may cause vision impairment and in severe cases permanent blindness.¹

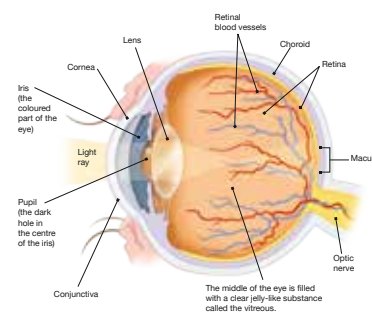
ROP is a major cause of preventable blindness in children worldwide: of 15 million children born worldwide in 2010, an estimated 53,800 developed sight-threatening ROP requiring treatment²

Why does ROP happen?

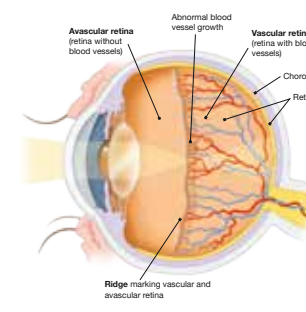
The retina is a thin layer of tissue that lines the back of the eye. The job of the retina is to convert light into electrical signals that travel along the optic nerve to the brain and help us to see.¹

For the retina to work properly, it needs proper vessels for a good blood supply. In an unborn baby, these vessels begin to develop at around 16 weeks, but this process is not completed until 40 weeks when the baby is full term. If your baby was born early (or prematurely), their retinal blood vessels may not have developed fully.

ROP happens when abnormal blood vessels grow in the retina, the light sensitive layer of tissue in the back of your baby's eye(s). In most babies, ROP is mild and will not require treatment. However, if ROP becomes severe, these abnormal vessels can cause vision loss if they are not treated.¹ Your baby's eye doctor will regularly examine your baby's eyes with special equipment (headlight and lens or a special camera) to see whether any treatment is required or not.



Side view of a healthy eye



Side view of an eye with ROP

Why is timely treatment of ROP important?

If your baby's eye doctor thinks your baby will benefit from treatment with EYLEA, the doctor will discuss this with you.

The eye doctor may recommend that you start treatment quite soon. This is because starting treatment as early as possible after diagnosis of treatment-requiring ROP can help minimise the damage to your baby's eyes and prevent future problems with your baby's vision.

Will ROP affect my baby's vision as they get older?

Your baby's eyesight will continue to be monitored as your baby grows. Babies with severe ROP will need regular appointments with an eye doctor. Only a very small percentage will experience impaired (or loss of) vision as they grow older, although they may be more at risk of developing other eye conditions such as a squint or the need for glasses later in life.¹

What is EYLEA (aflibercept)?

EYLEA is a solution that is injected into the eye and contains an active substance called aflibercept. EYLEA is used in premature babies to treat an eye condition called retinopathy of prematurity, or ROP.³ It may be helpful for you to know what to expect from the injection procedure, and this is described below.

How does EYLEA work?

Aflibercept, the active substance in EYLEA, works by blocking the activity of a group of factors known as Vascular Endothelial Growth Factor A (VEGF-A) and Placental Growth Factor (PlGF).³

EYLEA has been shown to stop the growth of new abnormal blood vessels in the eye, which often leak fluid or bleed. EYLEA may help to stop the progression of the disease and prevent complications like detachment of the retina, vision impairment and blindness.³

What to know before **your baby** is treated with **EYLEA**

EYLEA will be administered by your baby's eye doctor as an injection into one or both of your baby's eyes under aseptic (clean and sterile) conditions.³ It is important that your baby does not receive EYLEA if:³

- Your baby is allergic to aflibercept or any of the other ingredients in this medicine
- Your baby has an active or suspected infection in or around the eye (ocular or periocular infection)
- Your baby has severe inflammation of the eye (often indicated by pain, redness, or discharge from the eye)

If you think any of the above applies to your baby, please speak to your baby's eye doctor right away. You should also tell your baby's eye doctor if your baby is receiving, has recently received or might receive any other medicines.

What to expect from treatment with **EYLEA**

Knowing what to expect from the injection procedure may help you feel more at ease. If you have any questions about how EYLEA will be given, please speak to your baby's doctor.

Before the injection³

- Your baby's eye doctor who is experienced in giving eye injections will inject EYLEA into your baby's eye(s) under aseptic (clean and sterile) conditions
- Your baby's eye doctor may perform the injection procedure with your baby under local anaesthesia, under sedation or under general anaesthesia. This means a drug to eliminate the feeling of pain will be administered (anaesthetic), either via the vein (sedation or brief general anaesthesia) or as a local anaesthetic (applied to the eye area)
- Before the injection, your baby's eye doctor will use a disinfectant eyewash to carefully clean your baby's eye to prevent infection

What to expect from treatment with EYLEA

After the injection³

- Your baby's eye doctor will monitor the condition of your baby's eye(s)
- Depending on how your baby responds to treatment, your baby's eye doctor will decide if and when further treatment is needed
- If you observe any side effects in your baby, talk to your baby's eye doctor immediately
- If you have any further questions on the use of this medicine, please ask your baby's eye doctor

Possible side effects of EYLEA

Like all medicines, EYLEA can cause side effects, but not every baby will get them. It is important to identify side effects as quickly as possible, because when they are serious (like infection in the eye or retinal detachment), they need to be treated as soon as possible. Tell the baby's eye doctor immediately if you notice signs and symptoms in the baby's eye after injection, such as:

Side effects may include:	What to look out for
Infection or inflammation inside the eye	Redness/irritation, discharge from the eye, eyelid swelling, increased sensitivity to light
Clouding of the lens (cataract)	White pupil, poor vision (you may notice your child has difficulty recognising and following objects or people with their eyes)
Increase in eye pressure	Red eye, nausea, vomiting, increased tear production, discomfort and increased light sensitivity
Detachment, tear or bleeding of the retina, which is the light-sensitive layer at the back of the eye	White pupil, poor vision (you may notice your child has difficulty recognising and following objects or people with their eyes), newly observed crossed eyes (strabismus)

For a full list of side effects, refer to the **Patient Information Leaflet**, which is available via the QR code or the following link: https://go.bayer.com/EYLEA_GB_PIL



Reporting side effects

If you notice any side effects in your baby following the use of EYLEA, please talk to your baby's eye doctor, pharmacist or nurse. This also includes any side effects that are not listed in the package leaflet.

You are encouraged to report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or via the MHRA Yellow Card app available in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

Frequently asked questions

Do all premature babies get ROP?

No, but ROP is a common condition in premature babies. In most of these babies, ROP is only mild and will usually go away by itself. Severe forms of ROP will require treatment.

Does ROP affect both eyes?

In most cases, ROP affects both eyes and, if treatment is needed in both eyes, it will be given in both eyes. Occasionally, one eye will meet the criteria for treatment before the other. If this is the case, your baby's eye doctor will decide whether to treat them separately or at the same time.³

How long will my baby require treatment?

The treatment is started with a single injection per eye and may be given in both eyes on the same day. The doctor will have follow-up visits in the short term after treatment and in the long term. Depending on how your baby responds to the treatment, your baby's eye doctor will decide if and when additional treatment is needed. The treatment interval between the two doses injected into the same eye should be at least 4 weeks.³

Frequently asked questions

Are there any medicines my baby should avoid?

It is important to tell your baby's eye doctor if your baby is receiving, has recently received or might receive any other medicines.

What can I do to help protect my baby's vision after treatment has finished?

Once your baby has finished treatment with EYLEA, regular follow-up appointments are needed, during which your baby's eye doctor will monitor your baby's eyes and check for signs of problems.³

Make sure you receive a clear follow-up schedule and that you will be able to attend it. Contact your baby's eye doctor promptly if you have difficulty attending the visit.

If you have concerns about your child's vision as they get older, speak to your baby's eye doctor.

Notes and questions for my baby's eye doctor

Notes:

Notes and questions for my baby's eye doctor

Notes:

Notes and questions for my baby's eye doctor

Notes:

Notes and questions for my baby's eye doctor

Notes:

References

1. Great Ormond Street Hospital for Children NHS Foundation Trust: Information for Families. Retinopathy of prematurity (ROP). Available at: https://media.gosh.nhs.uk/documents/Retinopathy_of_prematurity_F1272_A4_bw_FINAL_Nov12.pdf. Accessed: May 2023.
2. Blencowe H, et al. *Pediatr Res* 2013;74:35–49.
3. EYLEA® (afibercept) Patient Information Leaflet.

