

Eydenzelt®▼ (aflibercept biosimilar) **Patient Guide**

Table of Contents

What is EYDENZELT?	4
What should I tell my doctor before starting my treatment with EYDENZELT?	5
How can I get ready for my appointment?	6
What can I expect after the treatment?	6
Does my treatment have side effects?	7
What if I have concerns or questions?	8

This educational material is provided by Celltrion Healthcare as a condition of the marketing authorisation of Eydenzelt in order to minimise important selected risks.

Your guide to EYDENZELT (aflibercept)▼

Aflibercept is used to treat conditions that affect your vision.

The guide has been produced for people who have been prescribed EYDENZELT (aflibercept solution for injection) for the treatment of one of the following eye diseases:

- the neovascular (wet) form of age-related macular degeneration (AMD)
- diabetic macular oedema (DME)
- macular oedema secondary to central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO)
- myopic choroidal neovascularisation (mCNV).

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this guide. You can also report side effects directly to HPRA Pharmacovigilance via www.hpra.ie.

You can also report side effects to Celltrion by email at medinfoie@celltrionhc.com or by phone on (01) 564 5074. By reporting side effects you can help provide more information on the safety of this medicine.

The guide is available in printed and digital format, both versions allow you to access an audio version via a smart device. The audio version is a readout of the text in this patient guide. More information is available to you in the Patient Information Leaflet (PIL).

This information can be accessed by visiting www.medicines.ie or by using the camera on a smart device to scan the relevant QR codes. This will direct the device to relevant information on the internet.

Patient Audio

QR code to Patient Audio



Patient Information Leaflet



Your doctor has prescribed EYDENZELT because you have been diagnosed with a condition that affects your vision.

What is EYDENZELT?

EYDENZELT contains aflibercept, which is a type of treatment known as an anti-VEGF. Anti-VEGF is an abbreviation for anti-vascular endothelial growth factor, and this is a description of how aflibercept works to protect your vision. Aflibercept blocks VEGF, and this action helps reduce the swelling in the retina and can lead to improvement and preservation of your vision.

EYDENZELT is a solution (a liquid) containing aflibercept that is injected into the eye. It is available in a 2 mg dose. Your doctor will recommend a treatment schedule for you and it is very important that you follow it.

Speak with your doctor or nurse if you have any questions or concerns about your treatment.

What should I tell my doctor before starting my treatment with EYDENZELT?

Before your treatment starts, make sure to tell your doctor and other health care providers if you:

- Have an infection in or around your eye.
- Currently have redness in your eye or if there is any pain in your eye.
- Think you may be allergic to iodine, any pain killers or any of the ingredients in EYDENZELT.
- Have had any issues or problems with eye injections before.
- Have glaucoma or a history of high pressure in your eye.
- If you see, or have seen, flashes of light or 'floaters' in your vision.
- Are taking any medications, with or without a prescription.
- Had or will have eye surgery within 4 weeks before or after your treatment.
- Are pregnant, planning to become pregnant or breastfeeding. There is very little information about the safety of using aflibercept in pregnant women. Aflibercept should not be used during pregnancy, unless the benefit outweighs the risk to the foetus. Discuss this with your doctor before treatment. Women of childbearing potential should use effective contraception during their treatment. If you are treated with aflibercept, you should continue to use effective contraception for at least three months after the last injection. Small amounts of aflibercept may enter into the breastmilk. The effects of aflibercept on a breast-fed newborn/infant is unknown. Use is not recommended during breastfeeding.

How can I get ready for my appointment?

Your doctor may ask you to use eye drops for a few days before your appointment. After your treatment, your vision may be blurry so you should not drive home. Plan to have a friend or family member take you to your appointment or arrange another way to get there and home again. On the day of your appointment, do not wear any makeup.

What can I expect after the treatment?

Your doctor may give you some eye tests after your injection. This may include a test that measures the pressure inside your eye. After your injection, your vision will be blurry so you should not plan to drive until after your vision returns to normal.

During the next few days you may get a bloodshot eye or see moving spots in your vision. These should clear within a few days and if they don't, or if they get worse, you should contact your doctor.

Some people might feel a little bit of pain or discomfort in their eye after their injection. If this does not go away or gets worse, you should contact your doctor.

Does my treatment have side effects?

Just like any medicine, aflibercept has the potential to cause side effects. Not everyone who is given an aflibercept injection will experience a side effect.

Contact your doctor immediately if you have any signs or symptoms listed in the table below as these could be signs of a serious complication with the treatment:

Condition	Some Potential Signs or Symptoms
Infection or inflammation inside the eye	• Eye pain or increased discomfort • Worsening eye redness • Sensitivity to light • Swelling of the eyelid • Vision changes such as sudden decrease in vision or blurring of vision
Clouding of the lens (cataract)	• Blurry vision • Seeing shadows • Less vivid lines and shapes • Colour vision changes (e.g. colours look 'washed out')
Increase in pressure in the eye	• Seeing halos around lights • Eye pain • Experiencing a red eye • Nausea or vomiting • Vision changes
A detachment or tear of a layer of the retina	• Sudden flashes of light • A sudden appearance or an increase of floaters • A curtain like effect over a portion of the visual area • Vision changes

For a full list of side effects, please refer to the relevant EYDENZELT Patient Information Leaflet (PIL). You can access the PIL using the QR code at the beginning of this guide, or by asking your doctor. The PIL is also available on www.medicines.ie.

If you get any side effects, which includes any possible side effects not listed in this guide, talk to your doctor, pharmacist or nurse. You can also report side effects directly to HPRA Pharmacovigilance via www.hpra.ie. Adverse events can also be reported to Celltrion Healthcare Ireland by phone on (01) 564 5074 or email at medinfoie@celltrionhc.com. By reporting side effects, you can help provide more information on the safety of this medicine.

What if I have concerns or questions?

If you have any concerns or questions, your doctor or nurse are the best people to speak to. They are very experienced and they know your individual situation so can provide you with the answers you need.

Useful contacts

Fighting Blindness

21 Hill Street, Dublin 1

Tel: 01 678 9004

www.fightingblindness.ie

Vision Ireland - Working for People with Sight Loss

Whitworth Road, Drumcondra, Dublin 9

Tel: 1800 911 250

www.vi.ie

Your eye care clinic is:

Contact:

Telephone:

Address:

Email: