

S A N D O Z

AFQLIR ▼ (aflibercept) 40mg/ml solution for injection

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.

YOUR GUIDE to AFQLIR®

AFQLIR is used to treat diabetic macular oedema (DMO)

Summary of important safety information

Contact your doctor as soon as possible if you experience any of the following symptoms after treatment with AFQLIR:

- If any eye pain or redness following the injection does not go away or is getting worse
- If your vision gets more blurred or you can't see as well as usual
- If you become more sensitive to light
- If you experience the sudden appearance of floaters, flashes of light and/or obscured vision

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information.

Please report **side effects** to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store

Alternatively you can report a side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Welcome to your AFQLIR guide

This booklet has been produced for people who have been prescribed the AFQLIR aflibercept solution for injection) for the treatment of **diabetic macular oedema (DMO)**

The booklet is available as a digital version and comes with an audio guide. The audio guide is a readout of the text in this patient booklet. This information can be accessed by visiting www.medicines.org.uk/emc.

More information is available to you in the Patient Information Leaflet (PIL).

Your doctor has prescribed AFQLIR because you have been diagnosed with DMO.

What is DMO?

Diabetic macular oedema (DMO) is a condition that occurs when fluid builds up in the retina. The retina is the layer of cells lining the back wall inside your eye. It senses light and lets you see by sending messages to the brain. The macula is an important area at the centre of the retina that allows you to see clear details of objects in front of you, like faces and words in books.

Diabetes can cause high or rapidly changing blood sugar levels. This can result in damage to small blood vessels around the body, and if this happens in the eye it may lead to swelling in the retina and blurry vision (DMO). The swelling is due mainly to higher than normal levels in the eye of a protein called VEGF. VEGF occurs naturally in the body and is involved in making blood vessels grow, but too much VEGF in the retina can trigger the growth of abnormal, leaky blood vessels. When vessels in the eye leak blood or other fluids this causes swelling of the retina. Over time without treatment, this process can lead to scarring in the macula and permanent central vision loss.

What is AFQLIR?

AFQLIR 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 AFQLIR works to protect your vision.

AFQLIR blocks VEGF, and this action helps reduce the swelling in the retina and can lead to vision improvement and maintenance of your vision.

AFQLIR is a solution (a liquid) that is injected into the eye.

For the treatment of DMO, AFQLIR is available in a 2 mg dose. Your doctor will recommend a treatment schedule for you and it is important that you follow it.

Who is AFQLIR for?

AFQLIR is for people who have been diagnosed with DMO.

What should your doctor know before you are treated with AFQLIR?

Before your AFQLIR treatment starts, make sure to tell your doctor or healthcare 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 painkillers or any of the ingredients in AFQLIR. The full list of ingredients can be found in the attached Package Leaflet
- Have had any issues or problems with eye injections before
- Have glaucoma or a history of high pressure in your eye
- 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 AFQLIR treatment
- Are pregnant, planning to become pregnant or breastfeeding. There is very little information about the safety of using AFQLIR in pregnant women. AFQLIR 2 mg should not be used during pregnancy, unless the benefit outweighs the risk to the baby. Discuss this with your doctor before treatment with AFQLIR.

Women of childbearing potential should use effective contraception during their treatment and for at least 3 months after the last injection of AFQLIR. Use of AFQLIR is not recommended during breastfeeding as small amounts of AFQLIR may enter into the breastmilk, and its effects on a newborn/infant are not known.

How can I get ready for my AFQLIR appointment?

Your doctor may ask you to take 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 to 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 my AFQLIR appointment?

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

If you use contact lenses, your doctor or nurse can advise you when you can start using them again.

Over the next few days you may get a bloodshot eye or see moving spots in your vision. Both of these should improve within days. 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 the pain does not go away or gets worse, you should contact your doctor.

Does AFQLIR have side effects?

Just like any medicine, AFQLIR has the potential to cause side effects. Not everyone who is given an AFQLIR 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	<ul style="list-style-type: none"> · 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)	<ul style="list-style-type: none"> · Blurry vision · Seeing shadows · Less vivid lines and shapes · Colour vision changes (e.g., colours looked “washed out”)
Increase in pressure in the eye	<ul style="list-style-type: none"> · 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	<ul style="list-style-type: none"> · Sudden flashes of light · A sudden occurrence or an increase of floaters (dark, floating spots) · A curtain-like effect over a portion of the visual area · Vision changes

For a full list of side effects, please refer to the AFQLIR Patient Information Leaflet (PIL). You can access the PIL by asking your doctor.

What if I have concerns or questions?

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

Your eye care clinic is:
Contact:
Phone:
Address:
E-mail:

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