

# Yesafili<sup>®</sup>

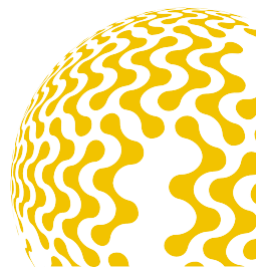
## Aflibercept

# Your guide to YESAFILI<sup>®</sup>

(aflibercept 40 mg/mL, solution injectable)

**YESAFILI<sup>®</sup> is used to treat  
diabetic macular oedema (DMO)**

▼ This medicine 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. See <https://yellowcard.mhra.gov.uk/> or how to report side effects



## Summary of important safety information

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

- 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.*

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

- The Yellow Card website [www.mhra.gov.uk/yellowcard](http://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 **suspected 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.*

*You can also report a suspected side effect by email:  
[medical.informationUK@biocon.com](mailto:medical.informationUK@biocon.com) and/or phone number: 0080008250910.*

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

## Welcome to your YESAFILI® guide

This booklet has been produced for people who have been prescribed YESAFILI® (aflibercept solution for injection) for the treatment of diabetic macular oedema, or DMO.

The aflibercept 2 mg dose has been studied in DMO. Your doctor gives you the YESAFILI® 2 mg dose, your doctor will use the YESAFILI® 40 mg/ml solution.

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](http://www.medicines.org.uk/emc).

For a digital version of this booklet, please visit  
<https://www.medicines.org.uk/emc>

For the audio guide, please visit  
<https://www.medicines.org.uk/emc>



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

For **UK** patients only:

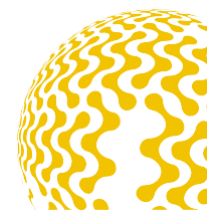
Please visit <https://www.medicines.org.uk/emc>

Your doctor has prescribed YESAFILI® 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 YESAFILI®?

YESAFILI® 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 YESAFILI® works to protect your vision.

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

YESAFILI® is a solution (a liquid) 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.

## Who is YESAFILI® for?

YESAFILI® is for people who have been diagnosed with DMO.

## What should your doctor know before you are treated with YESAFILI®?

Before your YESAFILI® 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 YESAFILI®. 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 YESAFILI® treatment
- Are pregnant, planning to become pregnant or breastfeeding. There is very little information about the safety of using YESAFILI® in pregnant women. YESAFILI® 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 YESAFILI®.



Women of childbearing potential should use effective contraception during their treatment with YESAFILI®.

If you are treated with the YESAFILI® 2 mg dose, you should continue to use effective contraception for at least 3 months after the last injection. Use of YESAFILI® is not recommended during breastfeeding as small amounts of YESAFILI® may enter into the breastmilk, and its effects on a newborn/infant are not known.

## How can I get ready for my YESAFILI® 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 YESAFILI® appointment?

Your doctor may give you some eye tests after your YESAFILI® 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.

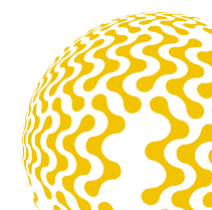
## Does YESAFILI® have side effects?

Just like any medicine, YESAFILI® has the potential to cause side effects. Not everyone who is given an YESAFILI® 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
<b>Infection or inflammation inside the eye</b>	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
<b>Clouding of the lens (cataract)</b>	Blurry vision Seeing shadows Less vivid lines and shapes Colour vision changes (e.g. colours looked 'washed out')
<b>Increase in pressure in the eye</b>	Seeing halos around lights Eye pain Experiencing a red eye Nausea or vomiting Vision changes
<b>A detachment or tear of a layer of the retina</b>	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 YESAFILI® Patient Information Leaflet (PIL). You can access the PIL by visiting <https://www.medicines.org.uk/emc> or 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.

<b>Your eye care clinic is:</b>	_____
<b>Contact:</b>	_____
<b>Telephone:</b>	_____
<b>Address:</b>	_____
	_____
	_____
<b>Email:</b>	_____

## Where can I find out more about DMO?

If you would like to find out more, or be put in touch with other people suffering from DMO, a list of useful contacts can be found below. You can write to these organisations, phone them or, if you have access to the internet, go to their websites. These organisations will have downloadable files of information which can be printed or read on the screen. They may also be able to provide their information in audio format for you to listen to.

### **The Macular Society**

**Helpline:** 0300 3030 111

**Address:** The Macular Society, PO Box 1870, Andover SP10 9AD

**Email:** [info@macularsociety.org](mailto:info@macularsociety.org)

**Website:** [www.macularsociety.org](http://www.macularsociety.org)

### **RNIB (Royal National Institute of Blind People)**

**Helpline:** 0303 123 9999

**Address:** Grimaldi Building, 154a Pentonville Road, London N1 9JE

**Email:** [helpline@rnib.org.uk](mailto:helpline@rnib.org.uk)

**Website:** [www.rnib.org.uk](http://www.rnib.org.uk)

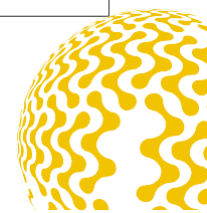
### **Diabetes UK**

**Helpline:** 0345 123 2399

**Address:** Wells Lawrence House, 126 Back Church Lane,  
London E1 1FH

**Email:** [helpline@diabetes.org.uk](mailto:helpline@diabetes.org.uk)

**Website:** [www.diabetes.org.uk](http://www.diabetes.org.uk)



# Notes

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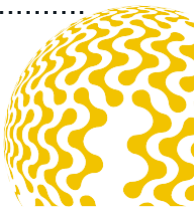
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YESAFILI® is used to treat diabetic  
macular oedema (DMO)

**Biosimilar Collaborations  
Ireland Limited**

Tel: 0080008250910 email:  
[medical.informationUK@biocon.com](mailto:medical.informationUK@biocon.com)

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