

# insight

ILUVIEN<sup>®</sup>



  
ILUVIEN<sup>®</sup>  
Fluocinolone Acetonide  
190 micrograms intravitreal  
implant in applicator

## Patient treatment support

Information for adult patients who have been prescribed ILUVIEN  
190 micrograms intravitreal implant in applicator (fluocinolone acetonide).



If you get any side effects, talk to your eye specialist, nurse, GP or pharmacist. This includes any possible side effects not listed in this booklet or the package leaflet that comes with your prescription. You can also report side effects directly via the Health Products Regulatory Authority at [www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects](http://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects). By reporting side effects you can help provide more information about the safety of this medicine.

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ILUVIEN is a treatment for vision loss associated with **Diabetic Macular Oedema** (sometimes referred to as DMO) when other available treatments have failed to help.

# Introduction

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You have been prescribed ILUVIEN to help improve your damaged vision or stop it from getting worse.

You may have questions about ILUVIEN and how it works, which is why this booklet has been developed. This booklet should not take the place of advice from your eye specialist, nurse, GP or pharmacist, who should always be your first point of contact.

Full information about ILUVIEN is available in the patient information leaflet that comes with your prescription but if you have any other questions or concerns you should raise these with your eye specialist, nurse, GP or pharmacist.



# What

Diabetic Macular Oedema, or DMO, is a condition that can affect the vision of some people with diabetes.

DMO occurs when tiny blood vessels in the retina are damaged due to persistently high blood glucose levels.

This damage can lead to the formation of new and abnormal blood vessels, which leak fluids into the retina. This can in turn cause the macula to swell (Macular Oedema).

# is DMO?

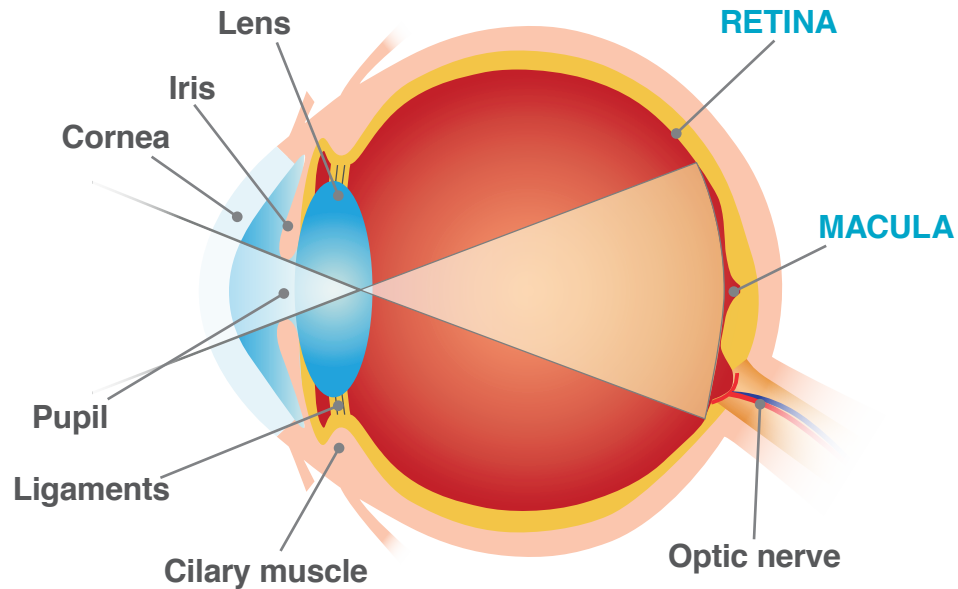
Swelling of the macula is what causes distorted central vision. Symptoms can include blurriness, difficulty reading and straight lines appearing wavy. Over time, DMO can lead to gaps in vision or severe loss of central vision.

## Reducing your risk

Good long-term management of your blood sugar levels and blood pressure will help to slow the progression of DMO. You can further reduce the risk of DMO progression by:

- Strict management of diabetes through medicine, insulin or other treatments, diet and exercise
- Having regular blood pressure checks
- Having regular cholesterol checks
- Having regular eye check-ups

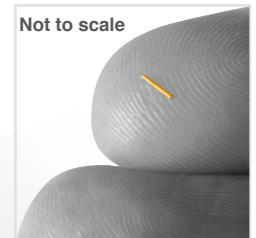
► Cross section of a human eye



**Retina:** The light-sensitive layer of the eye.

**Macula:** A small part of the retina responsible for sharp, detailed and central vision (the vision you experience when focusing straight ahead).

# What is ILUVIEN?



ILUVIEN is a tiny insert containing a corticosteroid medicine called **Fluocinolone Acetonide**.

**Corticosteroids:** Medicines prescribed to reduce inflammation and swelling in the body.

# How

# does ILUVIEN work?

ILUVIEN is given as a single injection into one eye. Even if both eyes are affected by DMO, ILUVIEN will only be administered into one eye initially. Your eye specialist will discuss any subsequent treatments on your second eye with you, but the procedure may be months later.

Once injected, the tiny insert releases very small quantities of fluocinolone acetonide for up to 3 years.

This release of a corticosteroid helps to reduce the inflammation and swelling that builds up in the macula, which can help to improve damaged vision or at the very least, help to prevent it from getting any worse. This improvement in vision may be noticeable as early as one week after treatment and could last for up to 3 years.



Not to scale

A close-up, partial view of a man's face on the left side of the page. He has light-colored hair and a slight smile, looking towards the right.

# Your

## Before your treatment

Your eye specialist will ask you about your health before they administer ILUVIEN to check that it's right for you.

# journey with ILUVIEN

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It is important to tell them everything about your health, even if it's not related to your eyes or diabetes, as it may affect whether ILUVIEN is suitable for you or not.



► **Important:**  
**You should tell your doctor:**

- If you think you might be allergic to fluocinolone acetonide, or any of the other ingredients in ILUVIEN (ask your eye specialist for more details)
- If you have an infection of any kind in or around your eye
- If you have been diagnosed with glaucoma, which is damage to the optic nerve
- If you are taking any medicines to thin the blood
- About any medication you are currently taking, have recently taken, or will take in the future (including non prescription medicines)
- If you have had a herpes simplex infection in your eye in the past (an ulcer on the eye that has been there a long time)
- If you are pregnant, planning to become pregnant or breast-feeding





## Receiving your treatment

An eye specialist will administer ILUVIEN into your eye via a single injection.

Before the injection, they will wash the eye thoroughly and use antiseptic eye drops to minimise the risk of infection. They will also give you local anaesthetic drops to minimise any pain and discomfort to you.

## Possible side effects

As with all medicines, ILUVIEN can cause side effects, although you won't necessarily get them. The most common side effects associated with the eye include:

- Increased pressure inside the eye
- Floaters (floating spots in your vision)
- Cataract (a clouding of the eye's natural lens, which may require eye surgery to correct)
- Bleeding in the white part of your eye or inside the eye
- Eye pain or irritation
- Reduced vision
- Eye surgery to relieve increased eye pressure or to remove the jelly-like material that fills the back of the eye

**You MUST talk to your GP, eye specialist, pharmacist or nurse if you have any side effects, even if they are not included in this guide. It is especially important for you to contact your doctors straight away if you notice any of the following side effects after being given ILUVIEN:**

- Increased eye pain or discomfort
- Worsening redness of your eye
- Flashing lights
- Sudden increase in floaters
- Partially blocked or impaired vision
- Increased sensitivity to light

## **Where else can you report side effects?**

**You can also report any side effects directly to:**

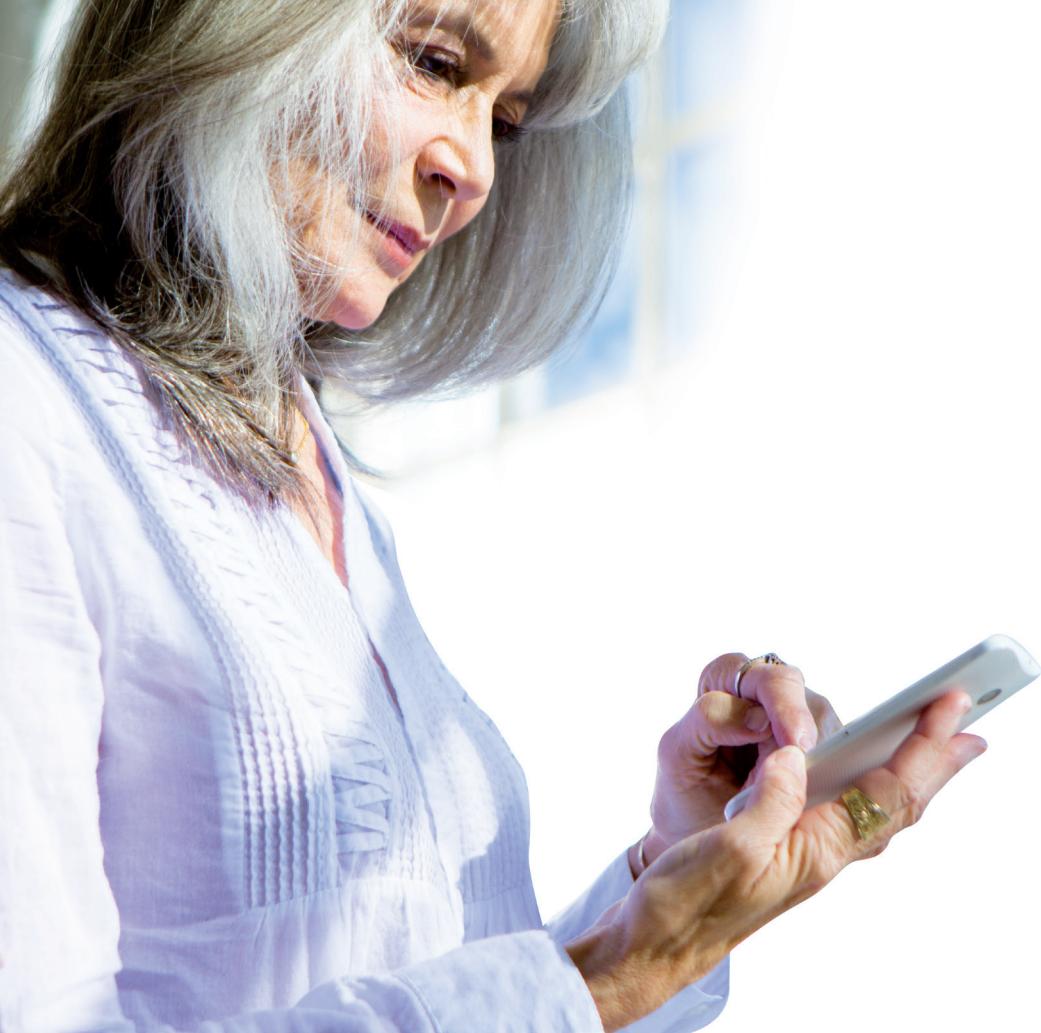
**HPRA Pharmacovigilance  
Earlsfort Terrace,  
IRL - Dublin 2**

**Tel: +353 1 6762517**

**Website: [www.hpra.ie](http://www.hpra.ie)**

**Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)**

**!** Please note that this is not a substitute for reporting side effects to your medical professional.



## After treatment

After the injection, your eye specialist may ask you to use antibiotic eye drops to prevent eye infections – make sure you follow their instructions carefully.

You may also experience some temporary blurred vision. If this happens do not drive or operate machinery until resolved.

Your healthcare team will schedule appointments to monitor your diabetes and check how ILUVIEN is working for you and your vision – it's really important that you attend these appointments. ILUVIEN has been shown to have a beneficial effect on vision for up to 3 years but an eye specialist will be able to advise on any further treatment should you require it. They may also want to monitor and check you for side effects that you may not otherwise notice yourself (e.g. increased pressure inside the eye).

**Make sure you have details for key members of your healthcare team, as it will help you to get in contact with them quickly should you need to, and take note of your upcoming appointments:**

Name	Telephone	Email

Appointments



**You may think of new questions or concerns that you wish to raise at your next appointment. Symptoms and side effects should be communicated to your eye specialist, nurse, GP or pharmacist straight away. You may want to keep track of any thoughts, questions or feelings using the following space to remind you at your appointment.**

## Treatment agreement for starting ILUVIEN® Therapy

You have been prescribed ILUVIEN as a treatment for the vision loss associated with diabetic macular oedema (sometimes referred to as DMO) when other available treatments have failed to help. The goal of your treatment with ILUVIEN is to help improve your vision or stop it from getting any worse.

As with any medication, there is a risk of side effects with ILUVIEN and in order to reduce the risk of any potential complications it is important to comply with regular monitoring appointments. You may not be aware of or notice potential complications, and so you will be monitored at least every 3 months, due to the extended duration of release of the

active ingredient, of approximately 3 years. During these appointments, an eye specialist will also be able to advise on any further treatment should you require it.

Your healthcare team will schedule these appointments with you to monitor your diabetes and check how ILUVIEN is working for you and your vision.

### What you need to do:

Maintain good control of your diabetes (per your doctor's recommendations and advice).

**Contact your doctors straight away if you notice any of the following side effects after being given ILUVIEN:**

- Increased eye pain or discomfort
- Worsening redness of your eye
- Flashing lights
- Sudden increase in floaters (floating spots in your vision)
- Partially blocked or decreased vision
- Increased sensitivity to light

Ensure you attend your monitoring appointments as scheduled by your healthcare team.

Dr. \_\_\_\_\_  
\_\_\_\_\_ and staff have explained the risks and benefits of ILUVIEN therapy for the treatment of diabetic macular oedema.

I, \_\_\_\_\_  
\_\_\_\_\_, understand that I must comply with the monitoring requirements and follow up appointments as advised.

Please sign this document, tear it out and hand it back to your healthcare provider.

Patient signature and date:

Healthcare provider and date:

# Further reading

## **Alimera Sciences**

For information on Alimera Sciences including the ILUVIEN patient information leaflet:

**[www.iluvien.ie](http://www.iluvien.ie)**

## **NCBI (National Council for the Blind of Ireland)**

The national sight loss organisation

**[www.ncbi.ie](http://www.ncbi.ie)**

**Information line: 01 830 7033**

## **Fighting Blindness**

Supporting people experiencing sight loss and empowering patients

**[www.fightingblindness.ie](http://www.fightingblindness.ie)**

**Helpline: 01 6789 004**

## **Diabetes Ireland**

The only national charity in Ireland dedicated to helping people with diabetes.

**[www.diabetes.ie](http://www.diabetes.ie)**

**Helpline 01 8428118 or Local 1850 909 909**