PACKAGE LEAFLET: INFORMATION FOR THE USER

ILUVIEN 190 micrograms intravitreal implant in applicator
(fluocinolone acetonide)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT ILUVIEN IS AND WHAT IT IS USED FOR

ILUVIEN is a tiny tube that is inserted into the eye and releases very small amounts of the active ingredient, fluocinolone acetonide, for up to 3 years. Fluocinolone acetonide belongs to a group of medicines called corticosteroids.

ILUVIEN is used to treat vision loss associated with diabetic macular oedema when other available treatments have failed to help. Diabetic macular oedema is a condition that affects some people with diabetes and causes damage to the light-sensitive layer at the back of the eye responsible for central vision, the macula. The active ingredient (the drug fluocinolone acetonide) helps to reduce the inflammation and the swelling that builds up in the macula in this condition. ILUVIEN can therefore help to improve the damaged vision or stop it from getting worse.

ILUVIEN is used to prevent relapses of inflammation of the back of the eye. This inflammation can cause floaters which are black dots or wispy lines that move across what you can see (‘field of vision’) or can cause loss of vision by damaging the part of the eye responsible for good vision, called the ‘macula’. The loss of vision may not improve unless the inflammation is treated. ILUVIEN helps to reduce the inflammation and the swelling that it can cause in the back of the eye. It can help improve your sight or stop it from getting worse. It may stop future attacks of inflammation.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ILUVIEN

You must not receive ILUVIEN:
- If you are allergic (hypersensitive) to fluocinolone acetonide or any of the other ingredients of this medicine (listed in section 6).
- If you have an infection of any kind in or around your eye.
- If you have glaucoma (high pressure inside your eye).

Warnings and precautions

- Before your ILUVIEN injection tell your doctor if:
    - You are taking any medicines to thin the blood
    - 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).

- ILUVIEN is given as an injection into the eye. Occasionally the injection may cause an infection inside the eye, pain or redness in the eye, or a detachment or tear of the retina. It is important to identify and treat these as soon as possible. Please tell your doctor immediately if you develop increased eye pain or discomfort, worsening redness of your eye, flashing lights and sudden increase in floaters, partially blocked vision, decreased vision or increased sensitivity to light after your injection.
- In some patients the eye pressure may increase with the possible development of glaucoma. This is something you may not notice; therefore you must be monitored by your doctor with visits to the clinic.
- In the majority of patients who have not yet had an operation for cataracts, a clouding of the eye's natural lens (a cataract) may occur after treatment with ILUVIEN. If this occurs your vision will decrease, and you are likely to need an operation to remove the cataract. Your doctor will help you to decide when is the most appropriate time to perform this operation, but you should be aware that until you are ready for your operation your vision may be as bad or worse than it was before you received your ILUVIEN injection.
- The injection of ILUVIEN into both eyes at the same time has not been studied and is not recommended. Your doctor should not inject ILUVIEN into both eyes at the same time.
- There is a potential for the ILUVIEN implant to move from the back to the front of the eye. There is an increased risk of this if you have had previous cataract surgery. A sign that the implant may have moved to the front of the eye could be distorted vision or other visual disturbance, or you may notice a change in the appearance of your eye at the front. Please tell your doctor if you notice anything unusual that may lead you to suspect the implant has moved.
- In patients with inflammation of the back of the eye, the eye pressure may decrease, but it usually lasts for a few days after the injection. This is something you may not notice therefore you must be monitored by your doctor within 2 to 8 days and with subsequent visits to the clinic.

Children and adolescents (below 18 years of age)

The use of ILUVIEN in children and adolescents has not been studied and is therefore not recommended.

Other medicines and ILUVIEN

Please tell your doctor if you are using or have recently used any other medicines, including medicines bought without a prescription.

Pregnancy, breast-feeding and fertility

- There is limited experience of using ILUVIEN in pregnant women or during breast-feeding; therefore the potential risks are unknown.
- There are no fertility data available. However, since ILUVIEN is inserted directly into the eye, effects on either male or female fertility is unlikely.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before ILUVIEN treatment.

Driving and using machines

After ILUVIEN treatment you may experience some temporary vision blurring. If this happens, do not drive or use machines until this resolves.

3. HOW ILUVIEN IS ADMINISTERED

The ILUVIEN injection will be administered by your eye doctor.

ILUVIEN is given as a single injection into your eye. Afterwards, your doctor will monitor your vision regularly.

Before the injection, your doctor will use antibiotic eye drops and wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to prevent any pain that the injection might cause.

Before and after the injection, your doctor may ask you to use antibiotic eye drops in order to prevent any possible eye infection. Please follow these instructions carefully.

If the effect of the implant wears off and your doctor recommends it, another implant may be injected into your eye. This applies only if you are administered Iluvien for the treatment of diabetic macular oedema.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ILUVIEN can cause side effects, although not everybody gets them.

With administration of ILUVIEN, there may be some side effects, mostly in the eye. Occasionally the injection may cause an infection inside the eye, pain or redness in the eye, or a detachment or tear of the retina. It is important to identify and treat these as soon as possible. Please tell your doctor immediately if you develop increased eye pain or discomfort, worsening redness of your eye, flashing lights and sudden increase in floaters, partial blocked vision, decreased vision or increased sensitivity to light after your injection. Other side effects may include increased or decreased eye pressure or clouding of the eye's natural lens. Increased pressure in the eye which damages the optic nerve (glaucoma) may be more likely if the pressure inside your eye is higher than average before treatment. Your doctor will discuss the risks of this with you before treatment. The symptoms you might experience and what you should do if you experience these symptoms are described in Section 2 of this leaflet (Warnings and precautions).

The following side effects may be seen with ILUVIEN:

Very common *(affects more than 1 in 10 patients)*
Increased eye pressure, clouding of the eye's natural lens (cataract) or eye surgery to correct the cataract.

Common *(affects between 1 and 10 in every 100 patients)*
Increased pressure in the eye which damages the optic nerve (glaucoma), detachment of the light-sensitive layer from the back of the eye (retinal detachment), bleeding in the white part of your eye or inside the eye, small particles or spots in vision (floaters), a feeling of looking through mist or fog, decreased pressure in the eye which causes sudden pain and blurred vision, Loss of your usual field of vision,eye pain or irritation, reduced vision, or eye surgery or procedure to relieve increased eye pressure or to remove the gel material that fills the back of the eye, increased protein and cells in the front of the eye due to inflammation, foreign body sensation in the eye, dry eye.

Uncommon *(affects fewer than 1 in every 100 patients)*
Blockage of the blood vessels at the back of the eye, new blood vessel growth inside the eye, ulcer on the white of the eye, changes in the gel material that fills the back of the eye, clouding of the bag holding

the lens of the eye, redness of the eye, itching or infection of the eye, thinning of the white outer layer of the eye, trauma to the eye from the injection of the medicine, unplanned movement of implant through white part of eye, and/or other complications from the injection, movement of the ILUVIEN implant from the back to the front of the eye, involuntary closing of the eyelids, achy and sore eyes with sudden inset of severe pain at times associated with blurred vison, deposits on the eye's outermost layer, painful eye condition caused by a scratch on the surface of the eye, swelling of the eye.

The most common non-visual side effect reported to be possibly caused by the drug or by the injection procedure is headache.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517 Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

5. HOW TO STORE ILUVIEN

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and inner wrap after EXP.
- Store below 30°C.
- Do not refrigerate or freeze.
- Do not open the sealed tray until just before application.
- Do not throw away any medicines via wastewater *or household waste*. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Dispose of the applicator safely in a biohazard sharps container

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ILUVIEN contains
- The active substance is fluocinolone acetonide.
- Each intravitreal implant contains 190 micrograms fluocinolone acetonide.
- The other ingredient is polyvinyl alcohol.
- The implant is a tiny tube made of polyimide and sealed with silicone adhesive on one end and polyvinyl alcohol on the other end.

What ILUVIEN looks like and contents of the pack

ILUVIEN consists of a tiny light brown tube (approximately 3.5 mm x 0.37 mm) which is preloaded in an applicator system. The preloaded applicator is placed in a polycarbonate tray and sealed with a peelable lid. Each sealed tray is provided in a carton which includes the package leaflet.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
United Kingdom: Alimera Sciences Limited
Royal Pavilion
Wellesley Road
Aldershot
Hampshire, GU11 1PZ
United Kingdom
UK Tel: 0800 019 1253

Ireland: Alimera Sciences Europe Limited
77 Sir John Rogerson's Quay
Dublin 2
Ireland
IE Tel: 1800 932 379

Manufacturer:
AndersonBrecon (UK) Limited
Wye Valley Business Park Hay-on-Wye
Hereford HR3 5PG, United Kingdom

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This medicinal product is authorised in the following Member States of the EEA under the invented name 'Iluvien':
Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Poland, Portugal, Spain, Sweden, United Kingdom.

Detailed information on this medicine is available on the website of the HPRA: https://www.hpra.ie and the MHRA: https://www.gov.uk/pil-spc

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The following information is intended for healthcare professionals only:

THERAPEUTIC INDICATIONS
ILUVIEN is indicated for the treatment of:

- vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies
- prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye

CONTRAINDICATIONS
An intravitreal implant with ILUVIEN is contraindicated in the presence of pre-existing glaucoma or active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

ILUVIEN is contraindicated in patients with:

- Hypersensitivity to the active substance or to any of the excipients
- Infectious uveitis

METHOD OF ADMINISTRATION
FOR INTRAVITREAL USE ONLY.

Treatment with ILUVIEN is for intravitreal use only and should be administered by an ophthalmologist experienced in intravitreal injections. The intravitreal injection procedure should be carried out under controlled aseptic conditions, which include use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anaesthesia and a broad-spectrum microbicide should be given prior to the injection.

The injection procedure for ILUVIEN is as follows:

1. Preoperative antibiotic drops may be administered at the discretion of the treating ophthalmologist.
2. Just prior to injection, administer topical anaesthesia over the injection site (inferotemporal quadrant recommended) as one drop followed by either a cotton-tipped applicator soaked in anaesthetic or as subconjunctival administration of adequate anaesthesia.
3. Administer 2-3 drops of adequate topical antiseptic into the lower fornix. The lids may be scrubbed with cotton-tipped applicators soaked with an adequate topical antiseptic. Place a sterile lid speculum. Have the subject look up and apply a cotton-tipped applicator soaked with an adequate antiseptic to the injection site. Allow 30-60 seconds for the topical antiseptic to dry prior to injection of ILUVIEN.
4. The exterior of the tray should ***not*** be considered sterile. An assistant (non-sterile) should remove the tray from the carton and examine the tray and lid for damage. If damaged, do not use unit.
   If acceptable, the assistant should peel the lid from the tray ***without touching the interior surface***.
5. Visually check through the viewing window of the preloaded applicator to ensure that there is a drug implant inside.
6. Remove the applicator from the tray with sterile gloved hands ***touching only the sterile surface and applicator***.
   The protective cap on the needle should not be removed until ILUVIEN is to be injected. Prior to injection, the applicator tip must be kept above the horizontal plane to ensure that the implant is properly positioned within the applicator.
7. To reduce the amount of air administered with the implant, the administration procedure requires two steps. Before injecting the needle in the eye, push the button down and slide it to the first stop (at the curved black marks alongside the button track). At the first stop, release the button and it will move to the UP position. If the button does not rise to the UP position, do not proceed with this unit.
8. Optimal placement of the implant is inferior to the optic disc and posterior to the equator of the eye. Measure 4 millimeters inferotemporal from the limbus with the aid of calipers.
9. Carefully remove the protective cap from the needle and inspect the tip to ensure it is not bent.
10. Gently displace the conjunctiva so that after withdrawing the needle, the conjunctival and scleral needle entry sites will not align. Care should be taken to avoid contact between the needle and the lid margin or lashes. Insert the needle in the eye. To release the implant, while the button is in the UP position, advance the button by sliding it forward to the end of the button track and remove the needle. Note: Ensure that the button reaches the end of the track before removing the needle.
11. Remove the lid speculum and perform indirect ophthalmoscopy to verify placement of the implant, adequate central retinal artery perfusion and absence of any other complications. Scleral depression may enhance visualisation of the implant. Examination should include a check for perfusion of the optic nerve head immediately after the injection. Immediate intraocular pressure (IOP) measurement may be performed at the discretion of the ophthalmologist.

Following the procedure, patients should be monitored for potential complications such as endophthalmitis, increased intraocular pressure, retinal detachments, and vitreous haemorrhages or detachments and ocular hypotony (observed up to 8 days post treatment). Biomicroscopy with tonometry should be performed between two and seven days after the implant injection.

Thereafter it is recommended that patients are monitored at least quarterly for potential complications, due to the extended duration of release of fluocinolone acetonide, of approximately 36 months.