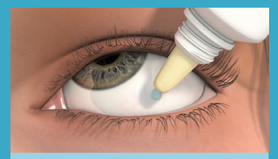
Quick reference guide: Using the ILUVIEN applicator

ILUVIEN is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema (DMO), considered insufficiently responsive to available therapies; and for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye.

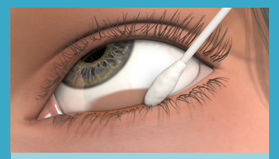
ILUVIEN must only be administered by a qualified Ophthalmologist experienced in intravitreal injections. Th intravitreal injection procedure should be carried out under controlled aseptic conditions using sterile gloves, a sterile drape and a sterile lid speculum (or equivalent). Prior to injectiom, preoperative antibiotic drops may be administered at the discretion of the ophthalmologist.

ILUVIEN®
Fluocinolone Acetonide
190 micrograms intravitreal implant in applicator

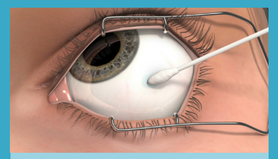
Preparing the patient for the intravitreal injection of ILUVIEN



Just prior to injection, administer topical **anaesthesia** over the injection site (inferotemporal quadrant recommended)



Administer 2-3 drops of adequate topical antiseptic into the lower fornix. The lids may be scrubbed with an adequate topical antiseptic.

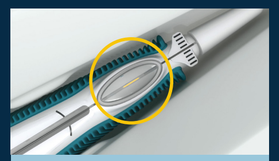


Place a **sterile lid speculum.** Apply a cotton-tipped applicator soaked with adequate antiseptic to the insertion site.

(!) Allow sufficient time for it to exert effect prior to the insertion of ILUVIEN.

Preparing the ILUVIEN applicator

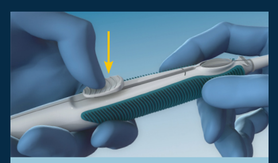
The exterior of the tray should not be considered sterile. Peel the lid from the tray **without touching the interior surface.**



Visually check through the viewing window to ensure that there is a drug implant inside.

Remove the applicator from the tray with sterile gloved hands touching only the sterile surface and applicator.

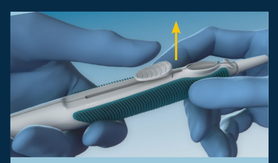
(!) Prior to injection, the applicator tip must be kept above the horizontal plane.



Incline the device with the tip facing upwards. Using the **thumb**, press **button down.**

With deliberate **downward pressure**,slide button forward in one **continuous motion** until it stops at curved black line.

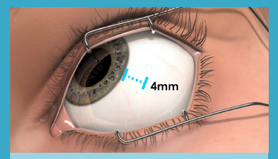
(!) The button will stop due to the plastic tab at end of the track.



Release button and it will rise to the up position.**The ILUVIEN applicator is now primed for the injection.**

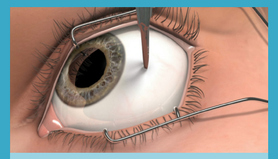
(!) If the button does not rise, do not proceed with this unit.

ILUVIEN insertion procedure

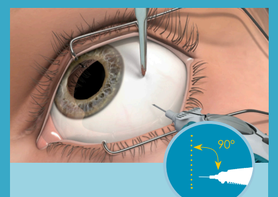


Optimal placement of the implant is inferior to the optic disc and posterior to the equator of the eye. **Measure 4mm inferotemporal from the limbus with calipers.**

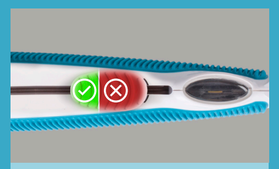
Maintain the injector tip **above the horizontal plane.** Carefully remove the protective cap from the needle and inspect the tip to ensure it is fit for injecting.



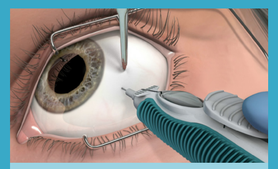
Gently displace the conjunctiva so that after withdrawing the needle the conjunctival and scleral entry sites will not align.



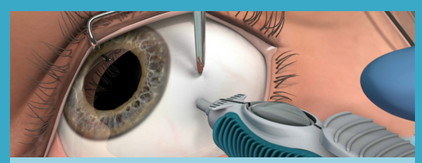
Insert the needle in the eye where measured at an angle of **90 degrees**.



Place finger **over bottom three lines** (as illustrated in green).

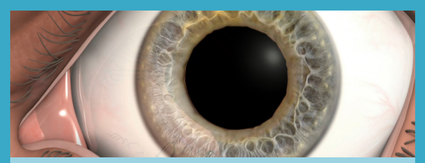


To release the implant, while the button is in the up position, **depress button slightly, then slide forward fully** until button **stops at the end of track.**



Ensure that the button reaches the end of the track before retracting the needle from the eye.

(!) A short pause (a 5 second count) before withdrawing the needle will help ensure the implant fully separates from the injector.



Remove the lid speculum and perform indirect ophthalmoscopy to verify placement of the implant, adequate retinal artery perfusion and absence of any other complications. Check for perfusion of the optic nerve head.

Patient monitoring

Ocular infection and IOP
*biomicroscopy with tonometry within 2 -7 days

Monitor VA and IOP quarterly

FAc · 2 -7 Days · 3 Months · 36 Months

Indirect ophthalmoscopy to see placement of implant

Perfusion of optic nerve head

Intraocular pressure (IOP)

Intravitreal insertions have been associated with endophthalmitis, increase or decrease in intraocular pressure, retinal detachments and vitreous haemorrhages or detachments. Patients should be instructed to report without delay any symptoms suggestive of endophthalmitis. Patient monitoring within 2 to 8 days following the insertion may permit early identification and treatment of ocular infection, increase or decrease in intraocular pressure or other complications. Biomicroscopy with tonometry should be performed between 2-7 days after the implant insertion.

It is recommended that intraocular pressure be monitored at least quarterly thereafter.

Use of intravitreal corticosteroids may cause cataracts, increased IOP, glaucoma, and may increase the risk of secondary infections.

The safety and efficacy of ILUVIEN administered to both eyes concurrently have not been studied. It is recommended that an implant is not administered to both eyes at the same visit. Concurrent treatment of both eyes is not recommended until the patient's systemic and ocular response to the first implant is known.

ILUVIEN injection video

SCAN ME!

ILUVIEN®
Fluocinolone Acetonide
190 micrograms intravitreal implant in applicator

Please review the complete ILUVIEN administration guide or instructional video prior to administering ILUVIEN.

PRESCRIBING INFORMATION

ILUVIEN® 190 micrograms intravitreal implant in applicator. Refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** intravitreal implant in applicator. Each implant contains 190 micrograms of fluocinolone acetonide. Light brown coloured cylinder, approximately 3.5mm x 0.37mm in size. Implant applicator with 25 gauge needle. **Indication:** ILUVIEN is indicated for the treatment of vision impairment associated with chronic diabetic macular oedema (DMO), considered insufficiently responsive to available therapies; and for prevention of relapse in recurrent non-infectious uveitis affecting the posterior segment of the eye. **Dosage and method of administration:** The recommended dose is one ILUVIEN implant in the affected eye. Administration in both eyes concurrently is not recommended. Each ILUVIEN implant releases fluocinolone acetonide for up to 36 months. In DMO, an additional implant may be administered after 12 months if the patient experiences decreased vision or an increase in retinal thickness secondary to recurrent or worsening diabetic macular oedema. Retreatments should not be administered unless the potential benefits outweigh the risks. Only patients who have been insufficiently responsive to prior treatment with laser photocoagulation or other available therapies for diabetic macular oedema should be treated with ILUVIEN. **Children under 18:** No relevant use. **Special populations:** No dosage adjustments are necessary in elderly patients, or those with renal or hepatic impairment. **Method of Administration:** ILUVIEN should be administered by an ophthalmologist experienced in intravitreal injections. **Educational Guidance:** Prior to administering ILUVIEN, physicians should familiarise themselves with the ILUVIEN Administration Guide. **Contraindications:** 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. Infectious uveitis or hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions:** Intravitreal injections have been associated with endophthalmitis, increase or decrease in intraocular pressure, retinal detachment and vitreous haemorrhage or detachment. Patients should be instructed to report without delay any symptoms suggestive of endophthalmitis. Patient monitoring within two to eight days following the injection may permit early identification and treatment of ocular infection, decrease or increase in intraocular pressure or other complication. It is recommended that intraocular pressure be monitored at least quarterly thereafter. Use of intravitreal corticosteroids may cause cataracts, increased intraocular pressure, glaucoma and may increase the risk of secondary infections. The safety and efficacy of ILUVIEN administered to both eyes concurrently have not been studied. It is recommended that an implant is not administered to both eyes at the same visit. Concurrent treatment of both eyes is not recommended until the patient's systemic and ocular response to the first implant is known. There is a potential for implants to migrate into the anterior chamber, especially in patients with posterior capsular abnormalities, such as tears. This should be taken into consideration when examining patients complaining of visual disturbance after treatment. **Interactions:** No interaction studies with other medicinal products have been performed. **Pregnancy and lactation:** There are limited data from the use of intravitreally administered fluocinolone acetonide in pregnant women. As a precautionary measure it is preferable to avoid the use of ILUVIEN during pregnancy. Although systemic exposure of fluocinolone is very low, a risk benefit decision should be made prior to use of ILUVIEN during breast-feeding. **Driving and using machines:** ILUVIEN has minor influence on the ability to drive and use machines. Patients may experience temporarily reduced vision after administration of ILUVIEN and should refrain from driving or using machines until this has resolved. **Undesirable effects:** Very common (≥1/10): cataract operation, cataract, increased intraocular pressure. Common (≥1/100 to <1/10): glaucoma, retinal detachment, optic disc haemorrhage*, vitreous haemorrhage, reduced visual acuity, visual field defect*, macula fibrosis*, conjunctival haemorrhage, blurred vision*, hypotony of eye*, vitreous floaters, anterior chamber cells*, vitreous opacities*, foreign body sensation in eyes*, dry eye*, photopsia*, eye pain, trabeculectomy, glaucoma surgery, vitrectomy, trabeculoplasty. Uncommon (≥1/1,000 to <1/100): endophthalmitis, headache, retinal vascular occlusion, optic nerve disorder, maculopathy, optic atrophy, conjunctival ulcer, iris neovascularisation, retinal exudates, vitreous degeneration, vitreous detachment, choroidal detachment*, corneal erosion*, corneal deposits, posterior capsule opacification, iris adhesions, blepharospasm*, eye oedema*, ocular hyperaemia, sclera thinning, eye discharge, eye pruritus, extrusion of implant, implant in line of sight, procedural complication, procedural pain, removal of extruded implant from sclera, device dislocation (implant migration). Consult the SmPC for full details of undesirable effects. **Overdose:** No case of overdose has been reported. **Legal classification:** Product subject to prescription which may not be renewed (A). Supply through pharmacies only. **Pack size:** One single use applicator. **Marketing Authorisation number:** PA22620/001/001. **Marketing Authorisation Holder:** Alimera Sciences Europe Limited, 77 Sir John Rogerson's Quay, Dublin 2, Ireland. Date of preparation of PI: July 2019

Reporting suspected adverse events is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie Adverse events should also be reported to Alimera Sciences Limited (telephone 1800932379) pvalimerasciences@alimerasciences.com

** Observed only in patients with Uveitis*

For medical enquiries please email: medicalinformation@alimerasciences.com

References: 1. ILUVIEN®, Summary of Product Characteristics.March 2019. Date of preparation: April 2020; IE-ILV-MMM-0068

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