ILUVIEN®
(fluocinolone acetonide intravitreal implant) 0.19mg

Administering ILUVIEN:
A Step-by-Step Guide

This guide is intended to be educational and describes the intravitreal injection procedure for ILUVIEN by a health care professional. This guide does not cover other aspects of patient care related to ILUVIEN, including diagnosis and treatment selection.

Not actual size.

INDICATIONS

ILUVIEN is a corticosteroid indicated for:

- the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
- the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease 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 glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

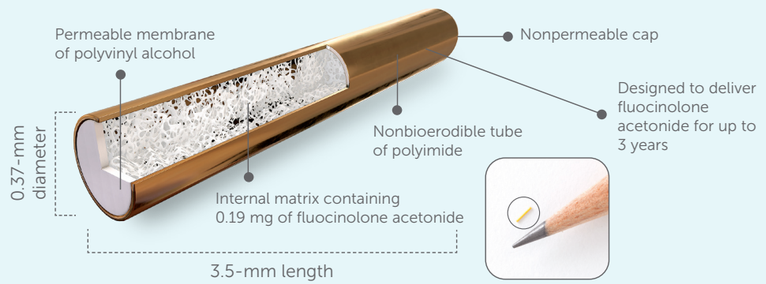
WARNINGS AND PRECAUTIONS

- **Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Patients may experience temporary blurred vision after injection of the implant.

Please see additional Important Safety Information throughout and full Prescribing Information.

ILUVIEN Is Designed to Last for Up to 3 Years[1]

ILUVIEN is designed to deliver a continuous low dose of fluocinolone acetonide for up to 3 years[1,2]



- Proprietary implant technology designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day and lasting for up to 3 years[1]
- Injector with a 25-gauge needle that intravitreally delivers the implant[1]

Overview

ILUVIEN is preloaded into a single-use applicator to facilitate injection of the implant directly into the vitreous.[1]

- The initial prescription and renewal of the medication order of ILUVIEN should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining[1]
- The intravitreal injection procedure should be carried out under aseptic conditions, which include the use of sterile gloves, a sterile drape, a sterile caliper, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a broad-spectrum microbicide should be given prior to the injection[1]
- Following the injection, patients should be monitored for changes in intraocular pressure and for endophthalmitis[1]

A trial of a demonstration applicator is highly recommended prior to the first administration of ILUVIEN. Please contact your local ANI Pharmaceuticals representative for a training on the ILUVIEN applicator.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

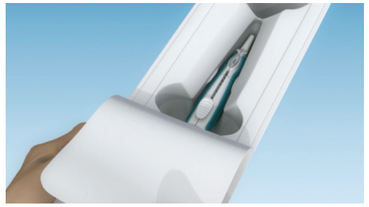
- **Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.
- **Cataracts:** The use of corticosteroids may result in posterior subcapsular cataract formation.
- **Delayed Corneal Wound Healing:** The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.
- **Corneal and Scleral Melting:** Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.

Preparation of the ILUVIEN Applicator

Step 1

- The exterior of the tray should **not** be considered sterile. An assistant who is nonsterile should remove the tray from the carton and examine the tray and lid for damage. **If damaged, do not use the unit**[1]

- If acceptable, the assistant should peel the lid from the tray **without touching the interior surface**[1]



- Do not touch the interior of the tray without a sterile-gloved hand[1]

IMPORTANT SAFETY INFORMATION (cont)

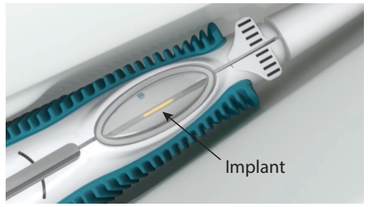
WARNINGS AND PRECAUTIONS (cont)

- **Bacterial Infections:** Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.
- **Viral Infections:** Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.
- **Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

Please see additional Important Safety Information throughout and full Prescribing Information.

Preparation of the ILUVIEN Applicator (cont)

Step 2



- Visually check, through the viewing window of the preloaded applicator, to ensure that there is a drug implant inside[1]

Step 3

- Remove the applicator from the tray with sterile-gloved hands, **touching only the sterile interior tray surface and applicator**[1]

- Prior to the injection, the applicator tip must be kept above the horizontal plane to ensure that the implant is properly positioned within the applicator[1]
- To reduce the amount of air administered with the implant, the administration procedure requires the tasks outlined in Step 4[1]

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS

Diabetic Macular Edema

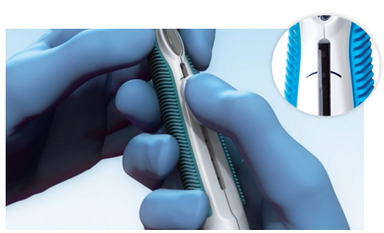
Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of ILUVIEN for diabetic macular edema include: cataract (82%), myodesopsia (21%), eye pain (15%), conjunctival hemorrhage (13%), posterior capsule opacification (9%), eye irritation (8%), vitreous detachment (7%), conjunctivitis (4%), corneal oedema (4%), foreign body sensation in eyes (3%), eye pruritus (3%), ocular hyperaemia (3%), optic atrophy (2%), ocular discomfort (2%), photophobia (2%), retinal exudates (2%), anterior chamber cell (2%), and eye discharge (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: anemia (11%), headache (9%), renal failure (9%), and pneumonia (7%)

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 34% of ILUVIEN patients versus 10% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 20% of ILUVIEN patients versus 4% of sham patients. 38% of the patients who received ILUVIEN were subsequently treated with IOP-lowering medications during the study versus 14% of sham patients. 5% of the patients who received ILUVIEN needed surgical intervention for elevated IOP versus 1% of sham patients

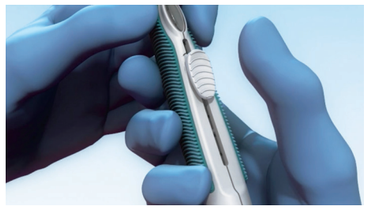
Step 4

- Before inserting the needle into the eye, remove the protective cap[1]

- Then gently push the applicator button down[1]



- Next, slide the applicator button to the first stop (at the curved black marks alongside the button track)[1]



- At the first stop, release the button, and it should move to the UP position. **If the button does not rise to the UP position, do not proceed with this unit**[1]

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS (cont)

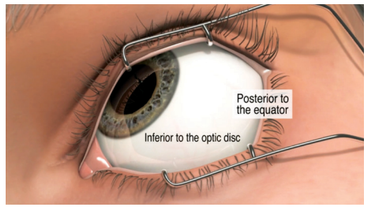
Diabetic Macular Edema (cont)

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN group and 19 months in the sham group. Among these patients, 80% of ILUVIEN subjects versus 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (median month 15 for both ILUVIEN group and for sham) of the studies.

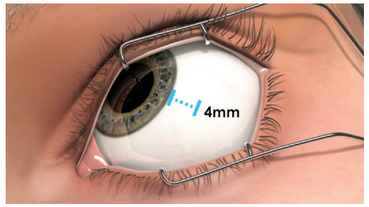
Please see additional Important Safety Information throughout and full Prescribing Information.

ILUVIEN Insertion Procedure

Step 5



- Optimal placement of the implant is inferior to the optic disc and posterior to the equator of the eye[1]



- Measure 4 millimeters inferotemporal from the limbus with the aid of calipers for point of entry into the sclera[1]

Step 6

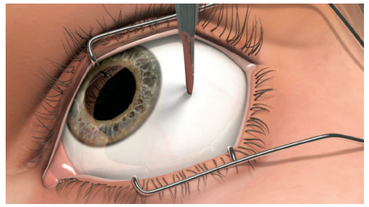
- Inspect the tip of the needle to ensure it is not bent[1]

IMPORTANT SAFETY INFORMATION (cont)

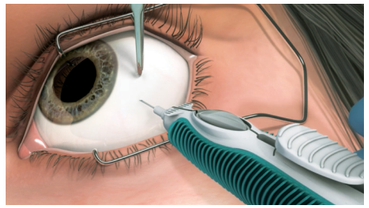
ADVERSE REACTIONS (cont)

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye
Ocular adverse reactions reported by greater than or equal to 1% of patients in the three combined clinical trials through 12 months following injection of fluocinolone acetonide intravitreal implant: cataract (56%), visual acuity reduced (15%), macular edema (11%), uveitis (10%), conjunctival hemorrhage (8%), eye pain (8%), hypotony of eye (7%), anterior chamber inflammation (5%), dry eye (4%), vitreous opacities (4%), conjunctivitis (4%), posterior capsule opacification (4%), ocular hyperemia (4%), vitreous haze (3%), foreign body sensation in eyes (3%), vitritis (3%), vitreous floaters (3%), eye pruritus (3%), conjunctival hyperemia (2%), ocular discomfort (2%), macular fibrosis (2%), glaucoma (2%), photopsia (2%), vitreous hemorrhage (2%), iridocyclitis (1%), eye inflammation (1%), choroiditis (1%), eye irritation (1%), visual field defect (1%), and lacrimation increased (1%). Non-ocular adverse reactions reported by greater than or equal to 2% of patients include: nasopharyngitis (5%), hypertension (3%), and arthralgia (2%).

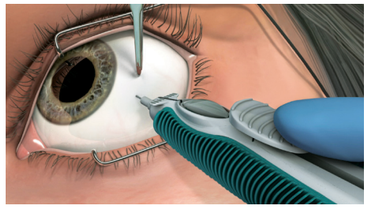
Step 7



- 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[1]

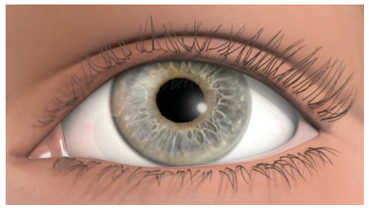


- Insert the needle through the conjunctiva and sclera[1]



- 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[1]
- Ensure that the button reaches the end of the track before removing the needle[1]

Step 8



- Remove the lid speculum and perform indirect ophthalmoscopy to verify the placement of the implant, adequate central retinal artery perfusion, and the absence of any other complications[1]

Please review the complete ILUVIEN administration video prior to administering ILUVIEN

Please see additional Important Safety Information throughout and full Prescribing Information.

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Monitoring Guidance

Not actual size.

- Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments[1]
- Following the injection, patients should be monitored for change in intraocular pressure and for endophthalmitis[1]
- Monitoring may consist of a check for perfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between 2 and 7 days following the injection. Patients should be instructed to report, without delay, any symptoms suggestive of endophthalmitis[1]

To learn more, please visit hcp.iluvien.com/administration

References: 1. ILUVIEN. Prescribing information. Alimera Sciences, Inc. **2.** Pons-Faudoa FP, Ballerini A, Sakamoto J, Grattoni A. Advanced implantable drug delivery technologies: transforming the clinical landscape of therapeutics for chronic diseases. *Biomed Microdevices*. 2019;21(2):47. doi:10.1007/s10544-019-0389-6

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS (cont)

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye (cont)
Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 22% of fluocinolone acetonide patients versus 12% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 12% of fluocinolone acetonide patients versus 3% of sham patients. 43% of the patients who received fluocinolone acetonide were subsequently treated with IOP-lowering medications during the study versus 41% of sham patients. 2% of the patients who received fluocinolone acetonide needed surgical intervention for elevated IOP versus 2% of sham patients.

Please see additional Important Safety Information throughout and full Prescribing Information.

ani Pharmaceuticals, Inc.

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