

ILUVIEN[®]
(fluocinolone acetonide
intraocular implant) 0.19mg

A guide to administering

ILUVIEN



Indication and Important Safety Information

INDICATION

ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg is 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.

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 injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the intravitreal injection.
- Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- 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.

ADVERSE REACTIONS

- In controlled studies, the most common adverse reactions reported were cataract development (ILUVIEN 82%; sham 50%), and intraocular pressure elevation of >10 mmHg (ILUVIEN 34%; sham 10%).

For additional information about ILUVIEN, please refer to the enclosed full Prescribing Information.

ILUVIEN is an intravitreal implant providing sustained-release delivery of a corticosteroid directly in the vitreous cavity for 36 months

- › Each implant contains 190 micrograms of flucinolone acetonide.
- › The implant measures approximately 3.5 mm x 0.37 mm in size.
- › ILUVIEN[®] (flucinolone acetonide intraocular implant) 0.19 mg is administered via a custom applicator with a 25-gauge needle.

Image shown is actual size



Preparing the patient for the intravitreal injection of ILUVIEN

- › The intravitreal injection procedure should be carried out under aseptic conditions, which include 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.

Important Safety Information

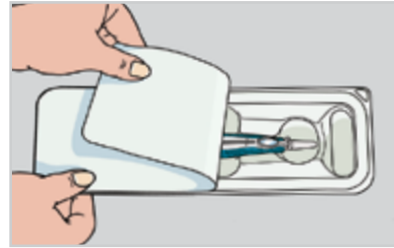
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Preparation of the ILUVIEN Applicator

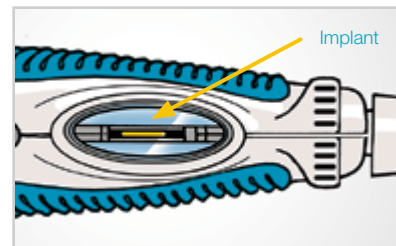
STEP 1

- › 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*.
 - Do not touch the interior of the tray without a sterile, gloved hand



STEP 2

- › Visually check through the viewing window of the preloaded applicator to ensure that there is a drug implant inside.



STEP 3

- › Remove the applicator from the tray with sterile gloved hands *touching only the sterile interior tray surface and applicator*.
 - The protective cap on the needle should not be removed until the patient is ready to be injected
 - Prior to injection, the applicator tip should be kept in the upright position to ensure that the implant is properly positioned within the applicator



STEP 4

- To reduce the amount of air administered with the implant, the administration procedure requires two steps.

- 1 Before inserting the needle into the eye, push the applicator button down and slide it forward to the first stop (at the curved black lines alongside the button track).
- 2 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

Figure 1



Figure 2



INSERTION PREPARATION POINTS

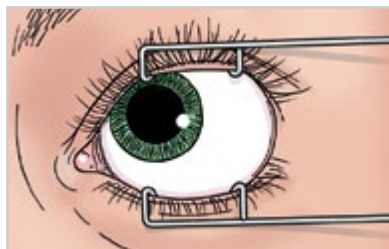
Applying Appropriate Pressure to Ensure Insertion Readiness

- To ensure that the applicator is prepared to insert the implant, appropriate pressure must be applied to the applicator button which may be achieved by using the thumb (as shown in Figure 1).
- With appropriate pressure, the button will not move past the first stop (noted by the curved black lines).
- Once the first-stop point is locked (as shown in Figure 2), remove the thumb from the button to allow the button to rise.
- If the button does not stop (and passes the curved black lines), it is possible that appropriate pressure was not applied, and that the implant is not in the correct position.

ILUVIEN Insertion Procedure

STEP 5

- › 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 for point of entry into the sclera.



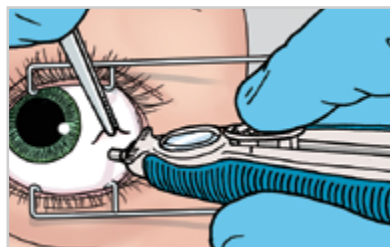
STEP 6

- › Carefully remove the protective cap from the needle and inspect the tip to ensure it is not bent.



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
 - Insert the needle through the conjunctiva and sclera
 - 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



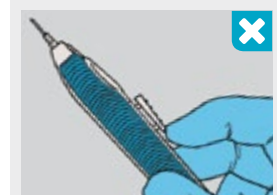
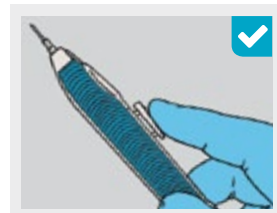
INSERTION TECHNIQUE POINTS

Achieving Optimal Insertion and Implant Placement

Optimal insertion and implant placement is most frequently achieved by a combination of precise finger positioning and applied pressure, as follows:

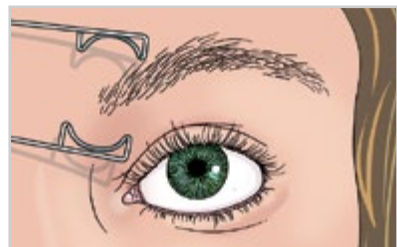
- Forward movement of the applicator button is optimized when the index finger is positioned toward the rear top portion of the applicator button (as shown in the “✓” illustration on the right).
- Applying slight downward pressure while pushing the applicator button forward provides optimal insertion and placement of the implant into the vitreous.
- Ensure the button reaches the end and stops before removing the needle.
- Positioning the index finger at the front or directly behind the applicator button (as shown in the “✗” illustrations on the right) is not recommended.
- Do not move the button backwards after the implant has been injected.

It is recommended to trial a demonstration applicator prior to first administering ILUVIEN[®] (fluocinolone acetonide intraocular implant) 0.19 mg. Alimera Sciences will provide training and demonstration applicators.



STEP 8

- › 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.



For additional information about ILUVIEN, please refer to the Important Safety Information on inside cover and the enclosed full Prescribing Information.

Follow-up after ILUVIEN insertion

- Following the injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. 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 two and seven days following the injection. Patients should be instructed to report without delay any symptoms suggestive of endophthalmitis.



Provide sustained, submicrogram levels of fluocinolone acetonide (FAc) from a single implant for 36 months

To learn more, please visit ILUVIEN.com

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