



Dear Healthcare Professional,

Thank you for your unsolicited request for information. Accompanying this letter is the following information you requested on ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg. If we can be of any further assistance, please contact our Medical Information department at 844-445-8843 between the hours of 9:00 AM to 8:00 PM ET (6:00 AM to 5:00 PM PT), Monday through Friday or via email at [iluvienmedinfo@anipharma.com](mailto:iluvienmedinfo@anipharma.com).

ILUVIEN 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.

ILUVIEN is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

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.

Please see the enclosed ILUVIEN Prescribing Information (PI) for detailed information including Warnings and Precautions and Adverse Reactions as well as the appropriate use of ILUVIEN.

This communication may contain confidential, proprietary, and/or privileged information. It is intended solely for the use of the addressee. If you are not the intended recipient, you are strictly prohibited from disclosing, copying, distributing or using any of this information. If you received this communication in error, please contact the sender immediately and destroy the material in its entirety, whether electronic or hard copy.

Thank you for your inquiry.

Sincerely,

A handwritten signature in black ink that reads "Steve Wu". The signature is written in a cursive, flowing style.

Steve Wu, PharmD

ANI Pharmaceuticals Medical Information

# Use of ILUVIEN<sup>®</sup> Intravitreal Implant in Retinal Vein Occlusion

## Abstract

- This document provides summary information pertaining to the off-label use of ILUVIEN<sup>®</sup> (fluocinolone acetonide [FAC] intravitreal implant) 0.19 mg in retinal vein occlusion (RVO) and treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (NIU-PS).
- This document provides a summary of an observational study of ILUVIEN, FAVOR, for off-label use in RVO

**Note that this document is for information purposes only and has been sent as a professional courtesy to provide you with data to assist in making your own practicing decisions. Please refer to the ILUVIEN (fluocinolone acetonide [FAC]) implant USPI for full [Prescribing Information](#) and safety information. ANI Pharmaceuticals does not recommend the use of its products in any manner inconsistent with the FDA-approved labeling. If you have further questions, please contact the Medical Affairs Department at <drugsafety@anipharma.com>.**

**To report an adverse event for any ANI Pharmaceuticals product, please call 1-800-308-6755 or contact the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Email: <drugsafety@anipharma.com>**

## Introduction

### Clinical Background

ILUVIEN 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 (IOP).<sup>1</sup>

ILUVIEN is indicated the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.<sup>1</sup>

ILUVIEN is not indicated for the treatment of RVO.

### Composition of ILUVIEN

ILUVIEN is a non-bioerodable intravitreal implant in a drug delivery system containing 0.19 mg FAc, designed to release FAc at an initial rate of 0.25 µg/day and lasting 36 months. Each ILUVIEN consists of a light brown 3.5mm x 0.37mm implant containing 0.19 mg of the active ingredient FAc and the following inactive ingredients: polyimide tube, polyvinyl alcohol, silicone adhesive, and water for injection.<sup>1</sup>

### Pharmacokinetics

In a human pharmacokinetic study of ILUVIEN, FAc concentrations in plasma were below the lower limit of quantitation of the assay (100 pg/mL) at all post-administration time points from Day 7 through Month 36 following intravitreal administration of a 0.2 mcg/day or 0.5 mcg/day FAc insert.<sup>1</sup>

### Clinical Pharmacology

ILUVIEN contains the corticosteroid FAc. Corticosteroids inhibit inflammatory responses to a variety of inciting agents including multiple inflammatory cytokines. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids are thought to act by inhibition of phospholipase A<sub>2</sub> via induction of inhibitory proteins collectively called lipocortins. It is postulated that these proteins control biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting release of the common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A<sub>2</sub>.<sup>1</sup>

### 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

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the intravitreal injection [see Patient Counseling Information (17)]. Patients may experience temporary blurred vision after injection of the implant.<sup>1</sup>

### **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.<sup>1</sup>

### **Cataracts**

The use of corticosteroids may result in posterior subcapsular cataract formation.<sup>1</sup>

### **Delayed Corneal Wound Healing**

The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.<sup>1</sup>

### **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.<sup>1</sup>

### **Bacterial Infections**

Prolonged use of corticosteroids may suppress the host immune 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.<sup>1</sup>

### **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.<sup>1</sup>

### **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.<sup>1</sup>

### **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.<sup>1</sup>

## Retinal Vein Occlusion—Interventional Study

ILUVIEN is not indicated for the treatment of retinal vein occlusion.

FAVOR (Fluocinolone Acetonide Intravitreal Inserts for Vein Occlusion in Retina [clinicaltrials.gov identifier NCT00770770]) was a randomized, double-masked, interventional study sponsored by Alimera Sciences that investigated visual acuity change from baseline at Month 3 following treatment with the ILUVIEN implant or 0.5 µg/day FAc in patients with RVO. The FAVOR study was conducted in 21 patients with macular edema associated with retinal vein occlusion. Baseline best-corrected visual acuity (BCVA) for patients treated with ILUVIEN was 47 Early Treatment Diabetic Retinopathy Study (ETDRS) letters. Approximately 55% of the randomized subjects in the ILUVIEN and 0.5 µg/day FAc treatment groups did not complete the study, largely due to early termination of the project. The change from baseline at Month 3 for the intention-to-treat population treated with ILUVIEN was +7 ETDRS letters.<sup>2</sup>

An additional PubMed literature search using the terms “fluocinolone acetonide,” “intravitreal implant,” “fluocinolone acetonide intravitreal implant,” “ILUVIEN,” combined with “retinal vein occlusion” between January 2020-December 1, 2024, was conducted, excluding all case reports with N≤2 eyes. According to the aforementioned search criteria, no additional relevant articles were identified for inclusion in this summary.

## References

1. ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, for intravitreal injection. Prescribing Information. ANI Pharmaceuticals, Inc. Updated 2023. Accessed January 17, 2025. <https://hcp.iluvien.com/prescribing-information/>
2. Data on file, ANI Pharmaceuticals 2025.