

Dear Healthcare Professional,

Thank you for your unsolicited request for information. Accompanying this letter is the following information you requested on YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 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 yutiqmedinfo@anipharma.com.

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

YUTIQ 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.

YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product.

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

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,



Steve Wu, PharmD
ANI Pharmaceuticals Medical Information

Earliest Timeframe for Administering an Additional YUTIQ® Implant

Abstract

- This document provides summary information pertaining to YUTIQ® (fluocinolone acetonide [FAC] intravitreal implant) 0.18 mg and its indication for use in the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye
- This document examines the evidence on earliest timing for administering an additional YUTIQ intravitreal implant
- This summary details the recurrence rates of uveitis and the necessity for additional therapy, drawn from two randomized controlled trials assessing the safety and efficacy of YUTIQ in treating non-infectious uveitis in the eye's posterior segment

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 YUTIQ (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@anipharmaceuticals.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.

Email: <drugsafety@anipharmaceuticals.com>

Introduction

Clinical Background

YUTIQ (FAc intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.¹

Composition of YUTIQ

YUTIQ is a non-bioerodible intravitreal implant in a drug delivery system containing 0.18 mg FAc, designed to release FAc at an initial rate of 0.25 mcg/day, and lasting 36 months. Each YUTIQ consists of a light brown 3.5mm x 0.37mm implant containing 0.18 mg of the active ingredient FAc and the following inactive ingredients: polyimide tube, polyvinyl alcohol, silicone adhesive, and water for injection.¹

Clinical Pharmacology

YUTIQ 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 A₂ 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 A₂.¹

Clinical Data for Uveitis Recurrence With YUTIQ

The efficacy and safety of YUTIQ for the treatment of non-infectious uveitis affecting the posterior segment of the eye were assessed in two randomized (2:1, YUTIQ: sham-injection), multicenter, double-masked, parallel-group studies, PSV-FAI-001 and PSV-FAI-005.¹⁻³ The primary efficacy endpoint in both trials was the proportion of patients who experienced a recurrence of uveitis in the study eye within 6 months of follow-up; recurrence was also assessed at 12 months. Recurrence of uveitis was defined as either deterioration in visual acuity, vitreous haze attributable to non-infectious uveitis, or the need for rescue medications.¹⁻³

Uveitis Recurrence Rates

Within 6 months of follow-up, the recurrence rates of uveitis were 18% in PSV-FAI-001 and 22% in PSV-FAI-005 for the YUTIQ group, compared with 79% in PSV-FAI-001 and 54% in PSV-FAI-005 for the sham group (Table 1).¹⁻³

Within 12 months of follow-up, the recurrence rates of uveitis were 28% in PSV-FAI-001 and 33% in PSV-FAI-005 for the YUTIQ group, compared with 86% in PSV-FAI-001 and 60% in PSV-FAI-005 for the sham group (Table 1).¹⁻³

	PSV-FAI-001		PSV-FAI-005	
	YUTIQ (n=87)	Sham (n=42)	YUTIQ (n=101)	Sham (n=52)
Eyes with recurrence within 6 months, n (%)	16 (18%)	33 (79%)	22 (22%)	28 (54%)
Difference (95% CI) in recurrence rates	60% (41%, 73%)		32% (15%, 48%)	
P-Value	<0.01		<0.01	
Eyes with recurrence within 12 months, n (%)	24 (28%)	36 (86%)	33 (33%)	31 (60%)
Difference (95% CI) in recurrence rates	58% (40%, 70%)		27% (9%, 43%)	

Table 1. Uveitis Recurrence Rates in PSV-FAI-001 and PSV-FAI-005 Studies
CI, confidence interval.

The use of multiple YUTIQ implants was not investigated during the 36-month clinical trial period of the presented studies above.^{2,3} However, patients in both treatment groups received standard local and/or systemic rescue therapy for recurrences.^{2,3} Consequently, the safety and efficacy of administering a second YUTIQ implant were not examined, and no information is available regarding the effects of using multiple implants.^{2,3}

Adjunctive Therapy for Recurrences

In PSV-FAI-001, through 36 months of follow-up, fewer patients treated with YUTIQ received rescue therapy than those in the sham group. Of YUTIQ-treated patients, 19.5% received ≥ 1 local injection compared to 69.0% of sham-treated patients. Additionally, 34.5% of YUTIQ-treated patients and 50.0% of sham-treated patients received at least one systemic treatment.² In PSV-FAI-005, 8.9% and 51.9% of patients treated with YUTIQ and sham, respectively, received ≥ 1 local injection; systemic steroids or immunosuppressive treatment was received in 31.7% and 32.7% of patients treated with YUTIQ and sham, respectively.³

A PubMed search was performed using the terms “fluocinolone acetonide,” “intravitreal implant,” “fluocinolone acetonide intravitreal implant,” “YUTIQ,” and “ILUVIEN,” combined with “uveitis” and “recurrence” along with their corresponding Medical Subject Heading (MeSH) terms to identify literature supporting uveitis recurrence with YUTIQ up to December 2024. The selection was limited to key studies in patients with non-infectious uveitis affecting the posterior segment of the eye treated with YUTIQ. Studies including case series (>2 eyes), and prospective studies of trials involving >2 eyes were considered to be of interest. According to the aforementioned search criteria, no additional relevant articles were identified for inclusion in this summary.

References

1. YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection. Prescribing Information. ANI Pharmaceuticals, Inc. Updated 2023. Accessed January 17, 2025. <https://yutiq.com/pi/>
2. Jaffe GJ, Pavesio CE; Study Investigators. Effect of a fluocinolone acetonide insert on recurrence rates in noninfectious intermediate, posterior, or panuveitis: three-year results. *Ophthalmology*. 2020;127(10):1395-1404.
3. Biswas J, Tyagi M, Agarwal M; PSV-FAI-005 Investigation Group. The 0.2- μ g/day fluocinolone acetonide intravitreal implant in chronic noninfectious posterior uveitis: a 3-year randomized trial in India. *Ophthalmol Sci*. 2023;4(1):100403.