

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

Efficacy and Safety of YUTIQ[®] Intravitreal Implants and Other Intravitreal Corticosteroid Implants

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 provides an overview of the efficacy and safety data for YUTIQ from the PSV-FAI 001 and PSV-FAI 005 studies

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

Response to Information Request

Due to differences in study design, direct comparisons of adverse event rates reported in clinical trials of a drug cannot be directly compared to the rates reported in clinical trials of other intravitreal corticosteroids.

Efficacy and Safety of YUTIQ

The efficacy of YUTIQ for the treatment of non-infectious uveitis affecting the posterior segment of the eye was assessed in two randomized (2:1, YUTIQ: sham-injection), multicenter, double-masked, parallel-group studies (PSV-FAI-001 and PSV-FAI-005).¹⁻³ Recurrence of uveitis was defined as either deterioration in visual acuity, vitreous haze attributable to non-infectious uveitis, or the need for rescue medications. In the intention-to-treat population, the proportion of subjects who experienced a recurrence of uveitis in the study eye within 12 months of treatment was statistically significantly lower in the FAc implant treatment group compared to the sham injection treatment group. Specifically, in the PSV-FAI-001 trial, there were 24 (27.6%) subjects in the FAc group vs 36 (85.7%) subjects in the sham group ($P<0.001$), and in the PSV-FAI-005 trial, there were 33 (32.7%) subjects in the FAc group compared to 31 (59.6%) in the sham group ($P=0.002$) (Table 1).^{1,4}

	PSV-FAI-001		PSV-FAI-005	
	YUTIQ n=87	Sham n=42	YUTIQ n=101	Sham n=52
Eyes with recurrence at 12 Months, n (%)	24 (28)	36 (86)	33 (33)	31 (60)
Difference in recurrence rates (95% CI)	58% (40%, 70%)		27% (9%, 43%)	

Table 1. Recurrence of Uveitis in Randomized Study Eyes at Month 12¹
CI, confidence interval.

The safety of YUTIQ was assessed using pooled results from PSV-FAI-001, PSV-FAI-005, and an additional single-masked safety study (Study 3). In the first 12 months of all three studies, intraocular pressure (IOP) elevations of ≥ 10 mmHg over baseline were seen in 22% of YUTIQ-treated eyes and 12% of sham-treated eyes, respectively (Table 2). IOP-lowering medications were prescribed for 43% of YUTIQ-treated eyes vs 41% of eyes in the sham group. Surgical interventions to lower IOP occurred in 5/226 (2%) of eyes in the YUTIQ treatment group and 2/94 (2%) of eyes randomized to sham treatment. Among eyes that were phakic at baseline, cataract occurred in 63/113 (56%) of YUTIQ-treated eyes and 13/56 (23%) of sham-treated eyes.¹

Adverse Reaction, n (%)	YUTIQ (n=226 eyes)	Sham (n=94 eyes)
IOP elevation ≥ 10 mmHg from baseline	50 (22)	11 (12)
IOP elevation >30 mmHg	28 (12)	3 (3)
Any IOP-lowering medication	98 (43)	39 (41)
Any surgical intervention for elevated IOP	5 (2)	2 (2)

Table 2. Summary of Elevated IOP-Related Adverse Reactions
IOP, intraocular pressure.

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.
4. Data on file, ANI Pharmaceuticals 2025.