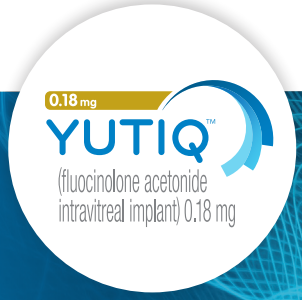
A Discussion Among Experts on the Treatment of Uveitis Affecting the Posterior Segment



Contributors

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Introduction

Uveitis is an umbrella term for any type of inflammation involving the uvea, and it is a leading cause of blindness worldwide.[1] In the United States, uveitis accounts for approximately 10% of preventable vision loss and has an estimated prevalence of 133 per 100,000 individuals.[1,2] The majority of cases (91%) are from a noninfectious etiology, of which 19% can be classified as nonanterior, encompassing intermediate, posterior, and panuveitis.[2]

Because uveitis encompasses so many different etiologies and presentations, there is no one standard uveitis patient. When all types of uveitis are considered, women are more likely to be affected than men; however, a patient with chronic noninfectious uveitis affecting the posterior segment is more likely to be a middle-aged (47.8 years old) man.[2,3] Patients with chronic noninfectious uveitis are more likely to have ocular comorbidities such as retinal disorders, glaucoma, and visual disturbances, as well as systemic autoimmune diseases, including, most commonly, rheumatoid arthritis and sarcoidosis. They are also likely to require more than 13 prescriptions and have more than 30 visits to a healthcare provider per year.[3]

Regardless of the anatomic location, steroids are considered the mainstay of noninfectious uveitis therapy, and the overall goal is to achieve long-term remission of inflammation using steroids as little as possible. Anterior uveitis is usually treated with topical steriods, whereas noninfectious uveitis affecting the posterior segment can be treated with oral or local (sub-Tenon or intraocular injections) steroids. If inflammation remains uncontrolled by steroids, they can be followed by immunosuppressives and/or biologics.[1] Another option for long-term control without resorting to systemic treatment is YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, an intraocular steroid implant.

INDICATIONS AND USAGE

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

IMPORTANT SAFETY INFORMATION

Contraindications

Ocular or Periocular Infections: 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.

Please see Important Safety Information for YUTIQ continued on pages 2, 4, and 6.

Please see Brief Summary for YUTIQ on page 8.

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What Is YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg?

YUTIQ is a US Food and Drug Administration–approved option for the treatment of chronic, noninfectious uveitis, affecting the posterior segment of the eye. It is a nonbioerodible implant that is injected into the vitreous and is designed to deliver a sustained release of fluocinolone acetonide for up to 36 months. Clinical trial data from 2 phase 3 sham-injection–controlled, double-masked studies showed that YUTIQ reduces the recurrence of uveitis at 6 and 12 months after injection (**Figure 1**) and extends the time to the first recurrence of uveitis within the first 12 months after injection (**Figure 2**).[4]

Figure 1. YUTIQ reduces uveitis recurrence at 6 and 12 months.

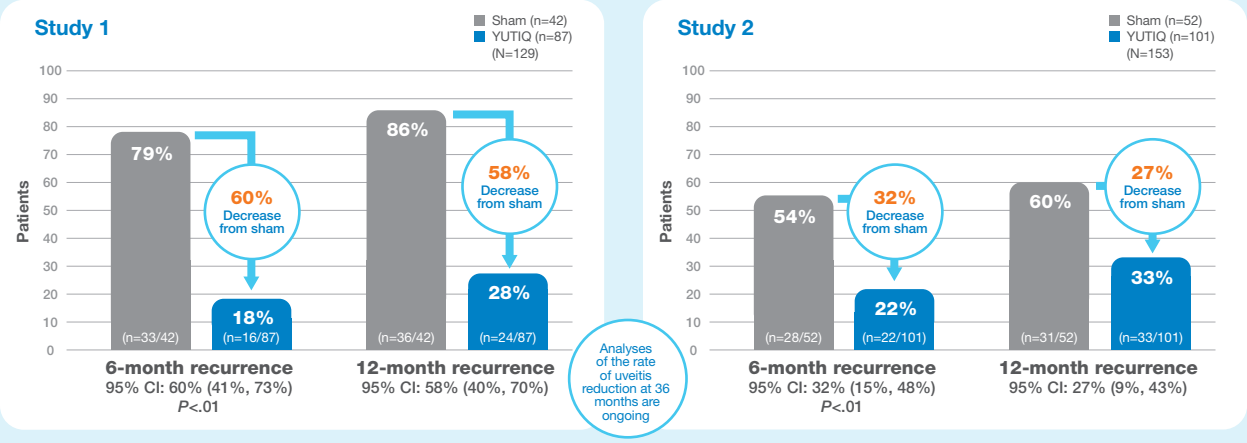
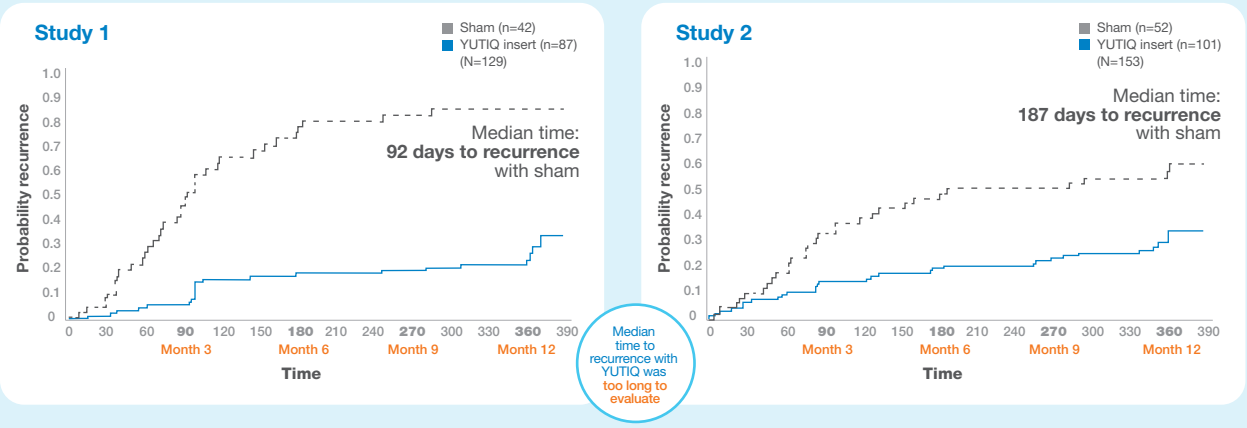


Figure 2. YUTIQ extends the time to first recurrence within 12 months.



IMPORTANT SAFETY INFORMATION (CONT'D)

Contraindications (cont'd)

Hypersensitivity: YUTIQ 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 YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments.

Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection.

Please see Important Safety Information for YUTIQ continued on front cover; pages 1, 4, and 6.

Please see Brief Summary for YUTIQ on page 8.

The Experts Discuss How to Use YUTIQ®
(fluocinolone acetonide intravitreal implant) 0.18 mg
in Existing Treatment Paradigms*

DR. SINGER: For patients with anterior chamber cell and/or flare indicating mild but persistent anterior inflammation, I usually start with topical steroids. If the patient is unresponsive, I switch to periocular steroid injections, especially if there is mild vitritis, but I try to avoid too many sequential periocular injections because I believe they increase IOP.

DR. DHOOT: Yes, I've also moved away from doing too many periocular steroid injections because of the POINT study, so I've shifted to intraocular steroid injections for forms of uveitis affecting the posterior segment.[5]

DR. SHARMA: When there's anterior uveitis, I start with topical steroids, but if the inflammation is refractory or not responding well, I will treat with oral steroids to ensure they respond well. If they flare when tapering, I will then consider either periocular or more likely intraocular steroids. However, I will also start systemic therapy to avoid repeated local injections.

DR. ALBINI: I tend to see local steroids that are injected either periocularly or intraocularly in 1 of 2 roles: either as a primary means to control ocular inflammation or as an adjunct to systemic medications, if the patient still has breakthrough ocular inflammation. Most systemics aren't great at controlling inflammation in the retina, so you often need to add a local steroid in those cases. For milder cases of intermediate uveitis, intraocular injection is great as a primary treatment, but it can also be used as adjunct medication for posterior or panuveitis. I still use intravitreal steroid implants for more serious cases because it's stronger, but they do have a more severe side effect profile and require surgical implantation, which makes them more complicated than injections.

DR. HARIPRASAD: The bolus effect from intraocular steroid injections helps to get the inflammation under control and as retina and uveitis specialists, we're all comfortable with its application and side effect profile. But, because it has a short duration of action, I find that for patients with long-term chronic uveitis, there is an inconsistent effect and they tend to have flares when the drug starts to run out.

DR. SINGER: Now that YUTIQ is available, I definitely use dexamethasone intravitreal implants before I use it. The currently available dexamethasone intravitreal implants are short acting, so you can get a better idea of how the patient's IOP will respond and if they'll have any steroid-related side effects. I like to use at least 2 intraocular injections to get the patient dry and then use YUTIQ to keep them dry. I also like to bridge them with the intraocular injection, so I'll wait 6 to 9 weeks after it before doing the YUTIQ injection. That way, the patient's inflammation is under control and the low-level sustained steroid release from the YUTIQ implant helps maintain quiescence. In my experience, if the eye isn't already quiet, YUTIQ will still work, but there is no immediate quieting; it is more of a slow and steady improvement.

DR. ALBINI: Yes, YUTIQ really shines in maintenance and helping to prevent recurrence, but the initial impact is not as great as that of the intraocular steroid injections, so, it's better to get inflammation under control in other ways. YUTIQ is not ideal for more difficult, acute cases; instead, it's better for maintenance and may reduce the need for adjunct medications.

DR. SHARMA: That's my thought, too. In my practice, I tell my patients that YUTIQ is for maintenance since it's a low dose and it may reduce the number of other treatments the patient needs. The easiest patients to use YUTIQ on are probably those who have had multiple intraocular steroid injections. That way, like Dr. Singer has said, you can get a better idea of how they'll react to YUTIQ, but over a shorter period of time.

*The opinions herein are those of the authors and are not the opinion of EyePoint or its representatives.

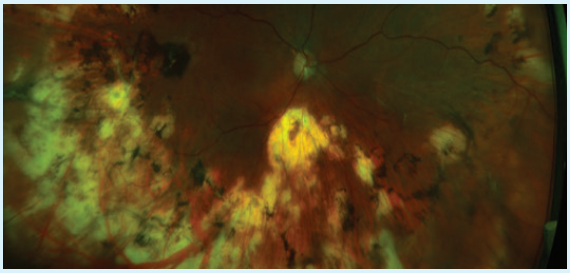
IOP=intraocular pressure.

Case Studies

Dr. Singer

A 67-year-old white male presented with a history of bilateral retinal detachment repair and chronic, bilateral, posterior uveitis. BCVA was 20/150 OD and 20/60 OS and IOP was 12 mm Hg OD and 14 mm Hg OS. He had 1+ vitreous cell OD and significant intravitreal cysts visible in color fundus (**Figure 3**). The patient was treated with repeated dexamethasone injections. The patient's vision had deteriorated to 20/200 OD and 20/80 OS and he had OU 2+ vitreous cells and snowballs. His IOP was 12 mm Hg OD and 13 mm Hg OS.

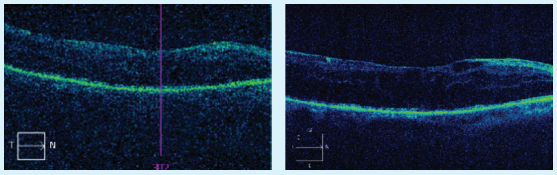
Figure 3. Color fundus at initial presentation, November 2016.



The patient was given a YUTIQ injection OD. Three months after treatment, BCVA in OD had improved to 20/60, vitreous cells decreased to trace, and IOP was 13 mm Hg. The patient's OCT also improved to 256 µm (**Figure 4A and 4B**). Based on these results, the patient's fellow eye was also treated with YUTIQ at this time. The patient is now undergoing regular follow-up on both eyes.

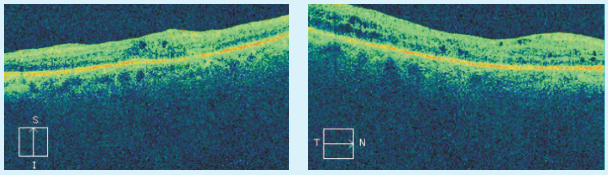
Figure 4. OCT imaging of OS. A) Immediately prior to YUTIQ injection. B) Three months after YUTIQ treatment.

A



Central Subfield Thickness (µm)	Cube Volume (mm^3)	Cube Average Thickness (µm)
453	14.1	395

B



Central Subfield Thickness (µm)	Cube Volume (mm^3)	Cube Average Thickness (µm)
256	9.4	262

BCVA=best-corrected visual acuity; CME=cystoid macular edema; OCT=optical coherence tomography.

IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions (cont'd)

Steroid-related Effects: Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids 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.

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 Important Safety Information for YUTIQ continued on front cover; pages 1, 2, and 6.

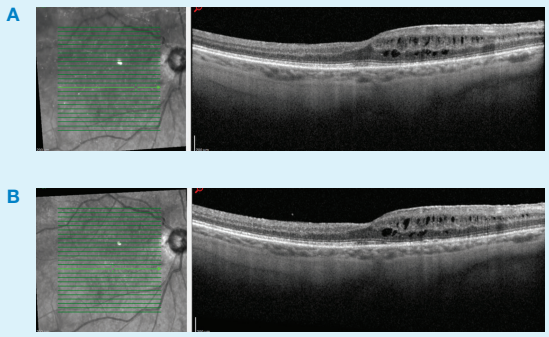
Please see Brief Summary for YUTIQ on page 8.

Case Studies

Dr. Dhoot

A 63-year-old white female presented with mild uveitis due to a history of scleral buckling and vitrectomy for retinal detachment/proliferative vitreoretinopathy OD. Her vision was CF OD and she had trace vitreous cells OD. She was treated with intravitreal steroid injections with limited success for several years. The patient was switched to YUTIQ, and she was followed up at 1 month. The patient's BCVA remained the same, but her OCT showed minimal improvement (**Figure 5**). While the initial follow-up visit showed some improvement, further follow-ups will be necessary to see the long-term effects of YUTIQ.

Figure 5. OCT imaging of OD. A) Immediately prior to YUTIQ injection. B) 1 month after YUTIQ treatment.

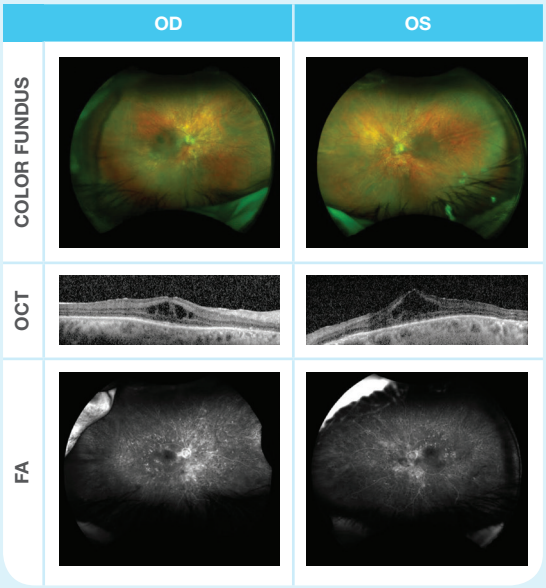


Dr. Albini

A 60-year-old white male presented with birdshot chorioretinopathy. His vision was 20/40 OU, but due to his occupation, he had difficulty following any treatment plan. Before the YUTIQ injection, the fundus photographs showed that the presence of CME that was worse OS than OD and the FA showed mostly window defects where he was starting to develop atrophy in the birdshot lesions and light vascularization. The OCT was also consistent with these findings (**Figure 6**).

A YUTIQ injection was initially performed only in OS because it had worse macular edema. At the 4-month follow up, OS showed modest improvement with CST decreasing from 410 µm to 351 µm and an improvement in BCVA from 20/40 to 20/30; however, these modest gains are significant for a patient who has previously been noncompliant with other treatment regimens. Since at this time OS had showed improvement, it was decided to inject YUTIQ into the fellow eye, and follow up for both eyes is on going.

Figure 6. Imaging before YUTIQ treatment.



CST=central subfield thickness; FA=fluorescein angiography.

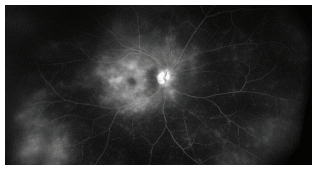
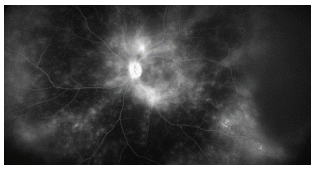
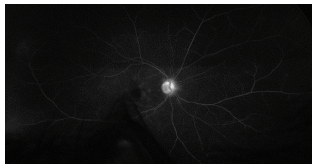
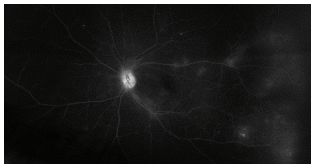
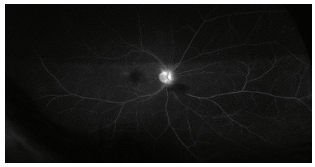
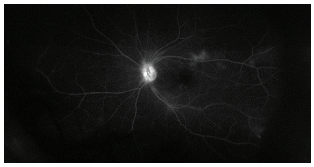
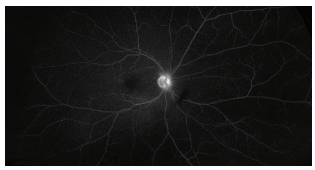
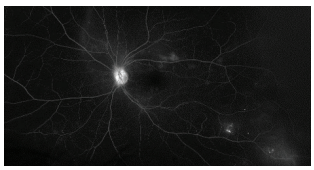
Case Studies

Dr. Sharma

A 59-year-old African American female presented with sarcoidosis with panuveitis and significant (2+) vitreous cell OU. At that time, the patient's BCVA was 20/80 OD and 20/40 OS. She was prescribed oral steroids followed by immunosuppressives and eventually adalimumab. This treatment course improved her vision to 20/60 OD and 20/30 OS and decreased vitreous cell to trace OU. But the patient was incompletely controlled with immunosuppressives and adalimumab, so she required repeated intraocular steroid injections OU to control her uveitis.

She received YUTIQ implants OU to provide long-term control over her uveitis. Immediately prior to the YUTIQ implants, the patient's BCVA was 20/125 OD and 20/25 OS and she had 0.5+ vitreous cell OD and 1+ vitreous cell OS. FA imaging showed that vascular leakage in both eyes improved at 6-week, 6-month, and 9-month follow-up visits (**Figure 7**). After treatment, her BCVA in both eyes was 20/25.

Figure 7. FA before YUTIQ and at each follow-up visit.

FOLOW-UP VISIT	OD	OS
BEFORE YUTIQ		
6 WEEKS		
6 MONTHS		
9 MONTHS		

IMPORTANT SAFETY INFORMATION (CONT'D)

Adverse Reactions

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure.

Please see Important Safety Information for YUTIQ continued on front cover; pages 1, 2, and 4.

Please see Brief Summary for YUTIQ on page 8.

Case Studies

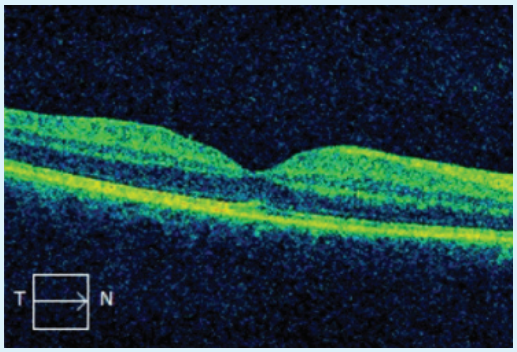
Dr. Hariprasad

A 34-year-old female presented with a 6-week history of blurred vision, light sensitivity, and redness in her right eye. She had been previously diagnosed with panuveitis and was started on prednisolone acetate drops every hour while awake. Her visual acuity was 20/40, her pupil was 3 mm and fixed, and the IOP was 11 mm Hg in OD. Slit lamp examination found +1 injection on her conjunctiva/sclera, 1-2+ anterior chamber cell, and 360° posterior synechiae with iris bombe. There also was pigment and fibrotic material on the anterior capsule and fibrotic material on the posterior capsule. Dilated fundus exam showed 2-3+ vitreous cell with haze, an elevated hyperemic disc, retinal nerve fiber layer hemorrhage, and a blunted foveal light reflex (**Figure 8A**). There were no abnormal findings OS.

The patient was continued on prednisolone acetate drops every hour while awake. Follow-up found her visual acuity was 20/30 and she had improved anterior chamber inflammation, but there was persistent 2-3+ vitreous cell with optic nerve edema and macular thickening. She was then prescribed YUTIQ to treat her persistent posterior uveitis. Follow-up after the YUTIQ injection showed some improvements in vitreous cell and haze (**Figure 8B**).

Figure 8. A) OCT of OD before YUTIQ injection. B) Color fundus of OD after YUTIQ injection.

A



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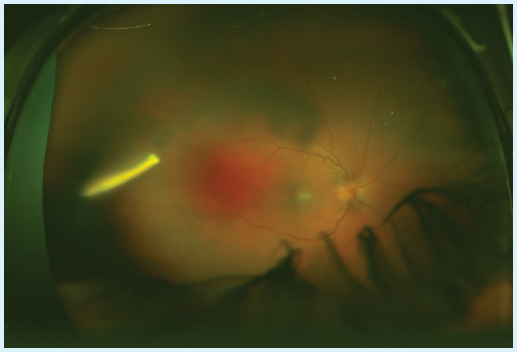

Injection Tips*

- **Dilate the eye—once it is injected, the YUTIQ implant is easier to visualize when the eye is dilated**
- **Use subconjunctival anesthesia—YUTIQ is injected once every 3 years, so it is worth the time to apply some subconjunctival anesthesia to make the injection process a bit easier on the patient**
- **Go straight in—the injector does not have a bevel, so twisting while inserting it is not necessary**
- **Control the injector—choke up on the injector to have more control over it**
- **Use a cotton swab or forceps—while injecting, use a cotton swab or forceps in the other hand to push the conjunctiva out of the way while also pushing in to increase the tension at the injection site**

*These tips are from various clinicians who have used YUTIQ and are not necessarily the view of the authors.

REFERENCES **1.** Foster CS, Kothari S, Anesi SD, et al. The Ocular Immunology and Uveitis Foundation preferred practice patterns of uveitis management. *Surv Ophthalmol.* 2016;61(1):1-17. **2.** Thorne JE, Suhler E, Skup M, et al. Prevalence of noninfectious uveitis in the United States: a claims-based analysis. *JAMA Ophthalmol.* 2016;134(11):1237-1245. **3.** Thorne JE, Skup M, Tundia N, et al. Direct and indirect resource use, healthcare costs and work force absence in patients with non-infectious intermediate, posterior or panuveitis. *Acta Ophthalmol.* 2016;94(5):e331-e339. **4.** YUTIQ [package insert]. EyePoint Pharmaceuticals. 2018. **5.** Thorne JE, Sugar EA, Holbrook JT, et al; Multicenter Uveitis Steroid Treatment Trial Research Group. Periocular triamcinolone vs. intravitreal triamcinolone vs. intravitreal dexamethasone implant for the treatment of uveitic macular edema: The PeriOcular vs. INTravitreal corticosteroids for uveitic macular edema (POINT) Trial. *Ophthalmology.* 2019;126(2):283-295.

SUPPLEMENT TO RETINA SPECIALIST

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04/2020
US-YUT-2000038

[INSERT]

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection
Initial U.S. Approval: 1963

BRIEF SUMMARY: Please see package insert for full prescribing information.

1. INDICATIONS AND USAGE. YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

4. CONTRAINDICATIONS. 4.1. Ocular or Periocular Infections. 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. **4.2. Hypersensitivity.** YUTIQ is contraindicated in patients with known hypersensitivity to any components of this product.

5. WARNINGS AND PRECAUTIONS. 5.1. Intravitreal Injection-related Effects. Intravitreal injections, including those with YUTIQ, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. Hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection *[see Patient Counseling Information (17) in the full prescribing information]*. **5.2. Steroid-related Effects.** Use of corticosteroids including YUTIQ may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids 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. **5.3. 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.

6. ADVERSE REACTIONS. 6.1. Clinical Studies Experience. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids including YUTIQ include cataract formation and subsequent cataract surgery, elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera. Studies 1 and 2 were multicenter, randomized, sham injection-controlled, masked trials in which patients with non-infectious uveitis affecting the posterior segment of the eye were treated once with either YUTIQ or sham injection, and then received standard care for the duration of the study. Study 3 was a multicenter, randomized, masked trial in which patients with non-infectious uveitis affecting the posterior segment of the eye were all treated once with YUTIQ, administered by one of two different applicators, and then received standard care for the duration of the study. Table 1 summarizes data available from studies 1, 2 and 3 through 12 months for study eyes treated with YUTIQ (n=226) or sham injection (n=94). The most common ocular (study eye) and non-ocular adverse reactions are shown in Table 1 and Table 2.

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

Ocular		
ADVERSE REACTIONS	**YUTIQ (N=226 Eyes) n (%)**	**Sham Injection (N=94 Eyes) n (%)**
Cataract[1]	63/113 (56%)	13/56 (23%)
Visual Acuity Reduced	33 (15%)	11 (12%)
Macular Edema	25 (11%)	33 (35%)
Uveitis	22 (10%)	33 (35%)
Conjunctival Hemorrhage	17 (8%)	5 (5%)
Eye Pain	17 (8%)	12 (13%)
Hypotony Of Eye	16 (7%)	1 (1%)
Anterior Chamber Inflammation	12 (5%)	6 (6%)
Dry Eye	10 (4%)	3 (3%)
Vitreous Opacities	9 (4%)	8 (9%)
Conjunctivitis	9 (4%)	5 (5%)
Posterior Capsule Opacification	8 (4%)	3 (3%)
Ocular Hyperemia	8 (4%)	7 (7%)
Vitreous Haze	7 (3%)	4 (4%)
Foreign Body Sensation In Eyes	7 (3%)	2 (2%)
Vitritis	6 (3%)	8 (9%)
Vitreous Floaters	6 (3%)	5 (5%)
Eye Pruritus	6 (3%)	5 (5%)
Conjunctival Hyperemia	5 (2%)	2 (2%)
Ocular Discomfort	5 (2%)	1 (1%)
Macular Fibrosis	5 (2%)	2 (2%)
Glaucoma	4 (2%)	1 (1%)
Photopsia	4 (2%)	2 (2%)

(continued)

[INSERT]

Table 1: Ocular Adverse Reactions Reported in ≥ 1% of Subject Eyes and Non-Ocular Adverse Reactions Reported in ≥ 2% of Patients

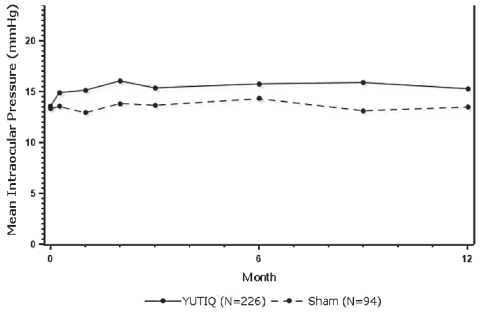
Ocular		
ADVERSE REACTIONS	**YUTIQ (N=226 Eyes) n (%)**	**Sham Injection (N=94 Eyes) n (%)**
Vitreous Hemorrhage	4 (2%)	0
Iridocyclitis	3 (1%)	7 (7%)
Eye Inflammation	3 (1%)	2 (2%)
Choroiditis	3 (1%)	1 (1%)
Eye Irritation	3 (1%)	1 (1%)
Visual Field Defect	3 (1%)	0
Lacrimation Increased	3 (1%)	0
Non-ocular		
ADVERSE REACTIONS	**YUTIQ (N=214 Patients) n (%)**	**Sham Injection (N=94 Patients) n (%)**
Nasopharyngitis	10 (5%)	5 (5%)
Hypertension	6 (3%)	1 (1%)
Arthralgia	5 (2%)	1 (1%)

1. Includes cataract, cataract subcapsular and lenticular opacities in study eyes that were phakic at baseline. 113 of the 226 YUTIQ study eyes were phakic at baseline; 56 of 94 sham-controlled study eyes were phakic at baseline.

Table 2: Summary of Elevated IOP Related Adverse Reactions

ADVERSE REACTIONS	YUTIQ (N=226 Eyes) n (%)	Sham (N=94 Eyes) n (%)
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%)

Figure 1: Mean IOP During the Studies



8. USE IN SPECIFIC POPULATIONS. 8.1 Pregnancy. Risk Summary. Adequate and well-controlled studies with YUTIQ have not been conducted in pregnant women to inform drug associated risk. Animal reproduction studies have not been conducted with YUTIQ. It is not known whether YUTIQ can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. YUTIQ should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. **8.2 Lactation.** Risk Summary. Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production. Clinical or nonclinical lactation studies have not been conducted with YUTIQ. It is not known whether intravitreal treatment with YUTIQ could result in sufficient systemic absorption to produce detectable quantities of fluocinolone acetonide in human milk, or affect breastfed infants or milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for YUTIQ and any potential adverse effects on the breastfed child from YUTIQ. **8.4 Pediatric Use.** Safety and effectiveness of YUTIQ in pediatric patients have not been established. **8.5 Geriatric Use.** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

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