INDICATION AND USAGE

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg contains a corticosteroid and is for the treatment of patients with chronic, non-infectious uveitis affecting the back of the eye.

IMPORTANT SAFETY INFORMATION

Do not take YUTIQ if:

- You have, or suspect you have, an eye infection
- If you have been told you are allergic to any of the ingredients in YUTIQ

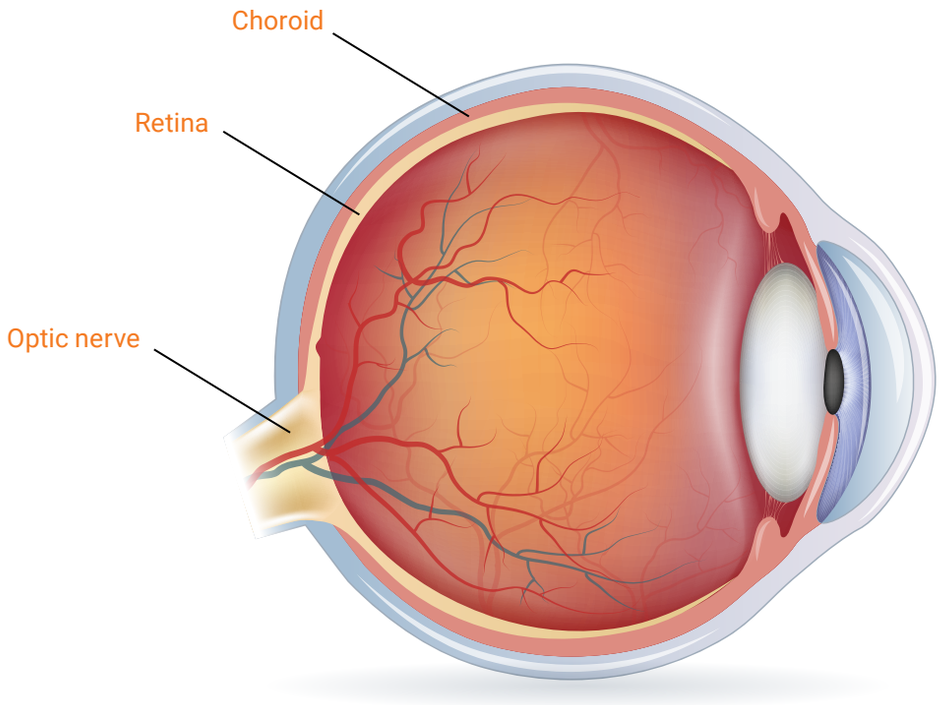
Please see Important Safety Information throughout and accompanying full Prescribing Information.

What is uveitis?

If you or a loved one has been diagnosed with posterior uveitis, understanding the condition is an important first step in managing symptoms. Uveitis (pronounced You-V-Eye-Tis) is a general term that refers to inflammation of the part of the eye called the uvea (YOU-V-ah).

In posterior uveitis, the inflammation is in the back of the eye and may affect the retina, choroid, and/or optic nerve. Posterior uveitis is the least common form of uveitis but is the form most associated with vision loss.

This diagram illustrates the parts of the eye posterior uveitis can affect



Common symptoms of uveitis

Because of the serious nature of posterior uveitis, you should tell your eye care professional if you have any of these symptoms:

Floaters

Small specks/ Flakes

Clouds

Blurred or decreased vision

When uveitis damages eye tissue, permanent vision loss can occur. In addition, serious eye conditions including glaucoma, cataracts, and retinal detachment may be complications of uveitis.

If you or a loved one have any of these symptoms, it's important to contact your eye care professional right away.

What causes uveitis?

Understanding the cause of posterior uveitis will help your eye care professional choose the right treatment. There are 2 types of uveitis—infectious and non-infectious. In some cases, the cause is unknown.

Infectious causes:

- Bacterial infection
- Fungal infection
- Parasitic infection
- Viral infection

Non-infectious causes:

- Autoimmune disorders
- Allergies
- Malignancies (tumors)
- Trauma

How is uveitis treated?

When treating posterior uveitis—either infectious or non-infectious—the primary goals are the same:

- Eliminate inflammation
- Relieve pain
- Restore vision loss
- Prevent serious complications such as blindness

Steroids

Many eyedrops or ointments will not reach the inflammation in the back of the eye, so steroid injections are used.

- If one eye is affected, steroid injections in the outside of the eye may help
  - They work for 3 months and may require multiple injections over time to keep posterior uveitis under control
- If both eyes are affected, steroid pills may be used
  - If you cannot take pills, or if the inflammation is severe, intravenous (IV) steroids may be prescribed

Intravitreal implants

A longer lasting treatment, called an intravitreal implant, uses a tiny rod to deliver a steady dose of steroid to the affected eye.

- Certain implants are surgically inserted requiring an incision and stitches; others are non-surgically inserted through a tiny needle and do not require stitches
- Typical implant lasts 3 months up to 3 years

Immune suppressant medicine

Other treatments include pills that more broadly reduce or suppress the body's immune system.

- Treatments include methotrexate, mycophenolate, azathioprine, and cyclosporine to reduce inflammation

Side effects may occur. It's important to discuss treatment risks with your eye care professional.

How can YUTIQ help?

If you or a loved one has chronic non-infectious posterior uveitis, YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg may be right for you. In scientific studies, YUTIQ was shown to help prevent uveitis from returning.

YUTIQ is the latest innovation in uveitis treatment

This tiny implant (shown actual size) is placed in the eye—delivering medicine directly to the eye.

YUTIQ is designed to deliver a steady release of medicine up to 36 months.

The short procedure is done right in your eye care professional's office. The non-bioerodible implant does not dissolve and does not need to be removed.

IMPORTANT SAFETY INFORMATION

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- You have, or suspect you have, an eye infection
- If you have been told you are allergic to any of the ingredients in YUTIQ

What you can expect from the YUTIQ procedure

The YUTIQ implant is inserted by an eye care professional during an in-office procedure.

Before your procedure, your eye is numbed with numbing drops and the eye receiving the implant is propped open with a device called a speculum (pronounced: Spek-U-Lum).

During your procedure, the YUTIQ implant will be inserted with a tiny needle. As the implant is being injected, you may feel some pressure on your eye.

After your procedure, your eye will be monitored for possible side effects right after the implant is inserted and then again 2 to 7 days later. It's important to keep up with regularly scheduled visits so your eye care professional can carefully monitor your condition.

IMPORTANT SAFETY INFORMATION *(cont'd)*

YUTIQ may cause serious side effects, including:
Injection-related effects, steroid-related effects and movement of the implant.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Not an actual patient.

Common questions and answers

Q: How long after receiving my YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg implant will it take until I see improvement?
A: In scientific studies, patients with YUTIQ had up to a 60% decrease in uveitis recurrence at 6 months. There were similar results at 12 months, where patients with YUTIQ had up to a 58% decrease in uveitis recurrence.

Q: Can I get another YUTIQ implant?
A: Speak with your eye care professional to determine what is the best course of treatment for you.

Q: How often do I have to see my eye care professional after the procedure?
A: Your eye care professional will determine when your appointments should be scheduled and these appointments are important to ensure your uveitis is being successfully treated.

Q: How long will the YUTIQ implant last?
A: YUTIQ is designed to provide up to 36 months of steady release of medicine directly to the back of the eye. Results may vary, that's why it's important to have regular follow-up visits with your eye care professional.

IMPORTANT SAFETY INFORMATION *(cont'd)*
Call your doctor if your eye becomes red, sensitive to light, painful or if your vision changes or becomes blurred.

You may experience temporary blurred vision. Do not drive or use machines until your vision clears.

EyePoint Assist℠

Helping you gain access to YUTIQ

Now that you and your eye care professional have determined that YUTIQ is right for you, EyePoint Assist is here to help. By offering a range of access and reimbursement services, we strive to make your experience with YUTIQ a positive one.

We will work on your behalf to:

- Coordinate health insurance coverage
- Determine associated out-of-pocket costs
- Determine eligibility for one of two financial support programs:
  - YUTIQ co-pay assistance program–designed to help make co-pays affordable if you have private or commercial insurance that covers YUTIQ for an approved indication
  - Patient assistance program–designed to help provide YUTIQ at no cost when you have no healthcare plan or your plan will not cover the cost of YUTIQ

Enroll at no cost. Call today. 1-833-EYEPOINT (1-833-393-7646)

For a full list of terms and conditions, please call 1-833-393-7646.

IMPORTANT SAFETY INFORMATION *(cont'd)*
The most common side effects in the eye were cataract and reduced clarity of vision. The most common side effects not related to the eye were upper respiratory infection, high blood pressure and joint pain.

If you are pregnant, become pregnant or consider breastfeeding after having received YUTIQ inform your doctor immediately.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Discover continuous calm in uveitis

Speak with your eye care professional to learn more about YUTIQ or visit **YUTIQ.com**.

INDICATION AND USAGE

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg contains a corticosteroid and is for the treatment of patients with chronic, non-infectious uveitis affecting the back of the eye.

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Call your doctor if your eye becomes red, sensitive to light, painful or if your vision changes or becomes blurred.

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The most common side effects in the eye were cataract and reduced clarity of vision. The most common side effects not related to the eye were upper respiratory infection, high blood pressure and joint pain.

If you are pregnant, become pregnant or consider breastfeeding after having received YUTIQ inform your doctor immediately.

Please see accompanying full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

EyePoint Pharmaceuticals

480 Pleasant Street, Suite B300, Watertown, MA 02472

06/2021
US-YUT-2100093

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use YUTIQ® safely and effectively. See full prescribing information for YUTIQ.

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection

Initial U.S. Approval: 1963

---------- INDICATIONS AND USAGE ----------

YUTIQ contains a corticosteroid and is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. (1)

---------- DOSAGE AND ADMINISTRATION ----------

- For ophthalmic intravitreal injection. (2.1)
- The intravitreal injection procedure should be carried out under aseptic conditions. (2.2)
- Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. (2.2)

---------- DOSAGE FORMS AND STRENGTHS ----------

Non-bioerodible intravitreal implant containing 0.18 mg fluocinolone acetonide in a drug delivery system. (3)

---------- CONTRAINDICATIONS ----------

- Ocular or periocular infections (4.1)
- Hypersensitivity (4.2)

---------- WARNINGS AND PRECAUTIONS ----------

- Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection. (5.1)
- 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. (5.2)
- The implant may migrate into the anterior chamber if the posterior lens capsule is not intact. (5.3)

---------- ADVERSE REACTIONS ----------

In controlled studies, the most common adverse reactions reported were cataract development and increases in intraocular pressure. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact EyePoint Pharmaceuticals US, Inc. at 1-833-EYEPOINT (1-833-393-7646) or FDA at 1 800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION **Revised: 5/2021**

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

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.

2. DOSAGE AND ADMINISTRATION

2.1. General Dosing Information

For ophthalmic intravitreal injection.

2.2. Administration

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.

The injection procedure for YUTIQ is as follows:

1. Just prior to injection, administer topical and/or subconjunctival anesthesia at the injection site (inferotemporal quadrant recommended).
2. Administer 2-3 drops of a broad-spectrum microbicide into the lower fornix. The lids may be scrubbed with cotton-tipped applicators soaked with a broad-spectrum microbicide. Place a sterile lid speculum. Have the patient look up and apply additional microbicide solution to the injection site. Allow 30-60 seconds for the topical antiseptic to dry prior to injection of YUTIQ.
3. Optimal placement of YUTIQ 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 callipers for point of entry into the sclera.
4. Using sterile procedure, open the sterile foil pouch containing YUTIQ.
5. Remove the YUTIQ applicator from the sterile pouch by grasping the barrel of the applicator; do not grasp the plunger.
6. Remove the black plunger stop from the plunger.
7. Carefully remove the protective cap from the needle and inspect the needle tip to ensure it is not bent.
8. Remove the trombone wire from the distal end of the needle. Prior to injection, keep the applicator tip above the horizontal plane to ensure that the YUTIQ implant does not fall out of the applicator.
9. 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.
10. Insert the needle through the conjunctiva and sclera up to the positive stop of the applicator.
11. Depress the plunger at the back of the applicator fully to deliver the YUTIQ implant into the back of the eye.
12. Remove the YUTIQ applicator from the eye and discard in biohazard sharps container.
13. Remove the lid speculum and perform indirect ophthalmoscopy to verify adequate central retinal artery perfusion, absence of any other complications, and to verify the placement of the implant. Scleral depression may enhance visualisation of the implant. Immediate measurement of intraocular pressure (IOP) may be performed at the discretion of the ophthalmologist.

Following the injection, patients should be monitored for change 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.

3. DOSAGE FORMS AND STRENGTHS

YUTIQ is a non-bioerodible intravitreal implant in a drug delivery system containing 0.18 mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day, and lasting 36 months.

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)]*.

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%)
Vitreous Hemorrhage	4 (2%)	0
Iridocyclitis	3 (1%)	7 (7%)
Eye Inflammation	3 (1%)	2 (2%)
Choroiditis	3 (1%)	1 (1%)

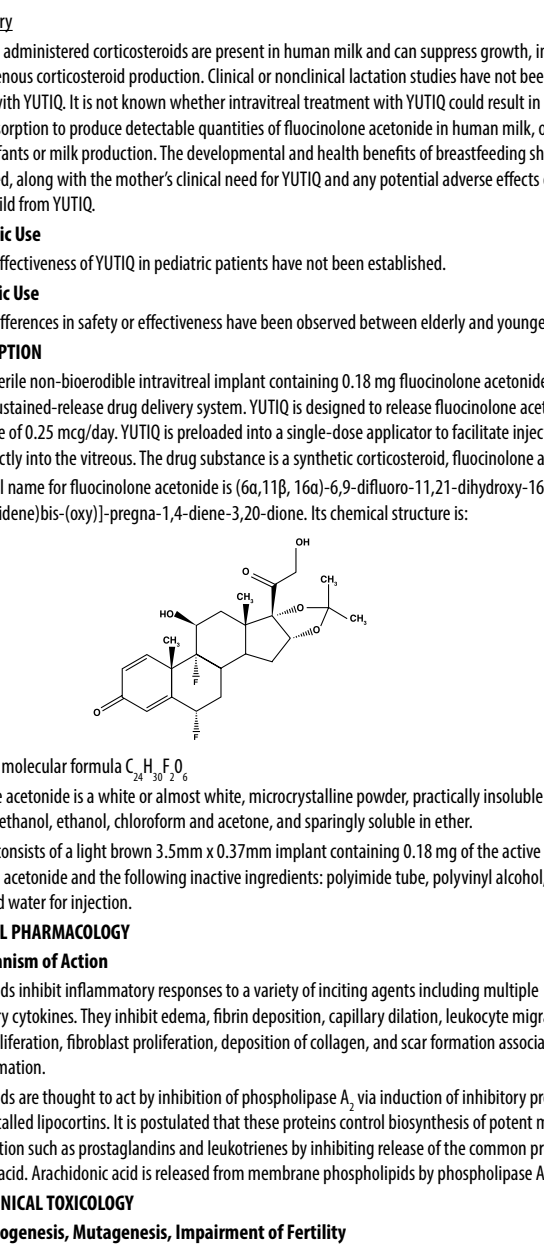
Eye Irritation	3 (1%)	1 (1%)
Visual Field Defect	3 (1%)	0
Lacrimation Increased	3 (1%)	0
Non-ocular		
ADVERSE REACTIONS	**YUTIQ (N=214 Patients) n (%)**	**Sham Injection (N=94 Patients) n (%)**
Nasopharyngitis	10 (5%)	5 (5%)
Hypertension	6 (3%)	1 (1%)
Arthralgia	5 (2%)	1 (1%)

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.

11. DESCRIPTION

YUTIQ is a sterile non-bioerodible intravitreal implant containing 0.18 mg fluocinolone acetonide in a 36-month sustained-release drug delivery system. YUTIQ is designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day. YUTIQ is preloaded into a single-dose applicator to facilitate injection of the implant directly into the vitreous. The drug substance is a synthetic corticosteroid, fluocinolone acetonide.

The chemical name for fluocinolone acetonide is (6α,11β, 16α)-6,9-difluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis-(oxy)]-pregna-1,4-diene-3,20-dione. Its chemical structure is:

MW 452.50; molecular formula $C_{24}H_{30}F_2O_6$

Fluocinolone acetonide is a white or almost white, microcrystalline powder, practically insoluble in water, soluble in methanol, ethanol, chloroform and acetone, and sparingly soluble in ether.

Each YUTIQ consists of a light brown 3.5mm x 0.37mm implant containing 0.18 mg of the active ingredient fluocinolone acetonide and the following inactive ingredients: polyimide tube, polyvinyl alcohol, silicone adhesive and water for injection.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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_2 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_2.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been conducted to determine the carcinogenic potential or the effect on fertility of YUTIQ.

Fluocinolone acetonide was not genotoxic *in vitro* in the Ames test (S. typhimurium and E. coli) and the mouse lymphoma TK assay, or *in vivo* in the mouse bone marrow micronucleus assay.

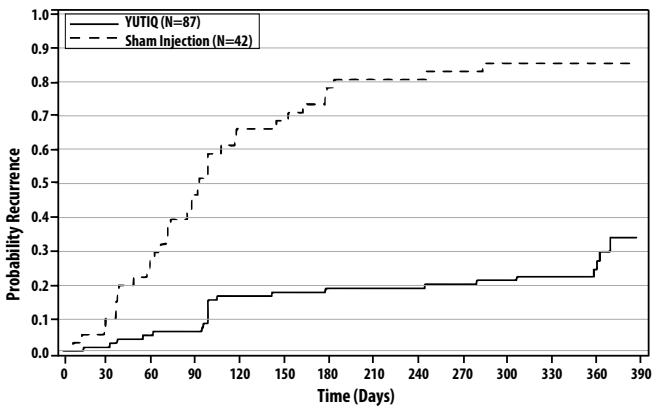
14. CLINICAL STUDIES

The efficacy of YUTIQ was assessed in two randomized (2:1, YUTIQ: sham-injection), multi-centre, double-masked, parallel-groups studies (NCT #01694186 and #02746991) that enrolled patients with non-infectious uveitis affecting the posterior segment of the eye. 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.

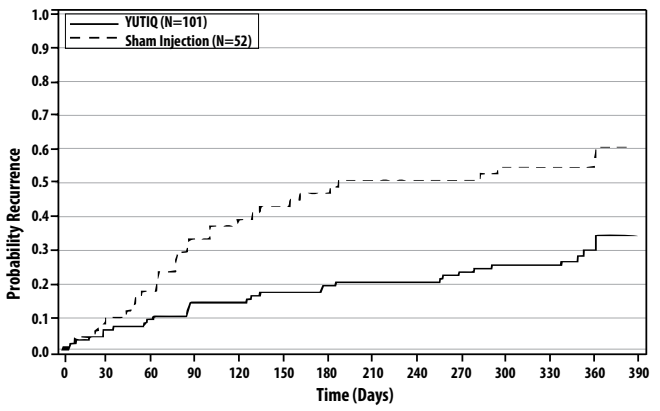
Table 3: Efficacy Results of Recurrence of Uveitis in Randomized Study Eyes

	Study 1		Study 2	
	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%)**	

Figure 2: Time to First Recurrence of Uveitis (ITT: All Randomized Patients)
Time to First Recurrence of Uveitis (ITT; all randomized subjects)
Study 1



Time to First Recurrence of Uveitis (ITT; all randomized subjects)
Study 2



16. HOW SUPPLIED/STORAGE AND HANDLING

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is supplied in a sterile single-dose preloaded applicator with a 25-gauge needle, packaged in a sealed sterile foil pouch inside a sealed Tyvek pouch inside a carton box.

NDC 71879-136-01

Storage: Store at 15° C to 30° C (59° F to 86° F).

17. PATIENT COUNSELING INFORMATION

Steroid-related Effects

Advise patients that a cataract may occur after treatment with YUTIQ. If this occurs, advise patients that their vision will decrease, and they will need an operation to remove the cataract and restore their vision. Advise patients that they may develop increased intraocular pressure with YUTIQ treatment, and the increased IOP may need to be managed with eye drops or surgery.

Intravitreal Injection-related Effects

Advise patients that in the days following intravitreal injection of YUTIQ, they are at risk for potential complications including, but not limited to, the development of endophthalmitis or changes in intraocular pressure.

When to Seek Physician Advice

Advise patients that if the eye becomes red, sensitive to light, painful, or develops a change in vision, they should seek immediate care from an ophthalmologist.

Driving and Using Machines

Inform patients that they may experience temporary visual blurring after receiving an intravitreal injection. Advise patients not to drive or use machines until this has been resolved.

Manufactured by:
EyePoint Pharmaceuticals US, Inc.
480 Pleasant Street
Watertown, MA 02472 USA
Patented.