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—infected and non-infected. 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
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

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.
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

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.

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

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YUTIQ may cause serious side effects, including:

Injection-related effects, steroid-related effects and movement of the implant.

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.

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

INDICATIONS AND USAGE

YUTIQ is indicated for the treatment of posterior subcapsular cataracts, 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, and retinal detachments. Patients should be monitored following the injection. (5.1)
- 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

Clinical studies have shown that YUTIQ is effective in the treatment of posterior subcapsular cataracts, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection. (5.1)

5.3. Risk of Implant Migration

Patients in whom the posterior capsule of the lens is absent or has a tear at risk of implant migration into the anterior chamber.

6. ADVERSE REACTIONS

Clinical studies have shown that YUTIQ is effective in the treatment of posterior subcapsular cataracts, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection. (5.1)

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Ocular %</th>
<th>Non-Ocular %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract</td>
<td>63/113 (56%)</td>
<td>13/56 (23%)</td>
</tr>
<tr>
<td>Visual Acuity Reduced</td>
<td>33/15 (21%)</td>
<td>11/7 (16%)</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>25/11 (23%)</td>
<td>33/7 (49%)</td>
</tr>
<tr>
<td>Iritis</td>
<td>22/19 (12%)</td>
<td>30/24 (25%)</td>
</tr>
<tr>
<td>Compromised Hemorrhage</td>
<td>17/8 (5%)</td>
<td>5/7 (7%)</td>
</tr>
<tr>
<td>Veno Pals</td>
<td>17/8 (5%)</td>
<td>12/10 (9%)</td>
</tr>
<tr>
<td>Hypopyon</td>
<td>16/7 (5%)</td>
<td>7/1 (1%)</td>
</tr>
<tr>
<td>Anterior Chamber Inflammation</td>
<td>12/7 (8%)</td>
<td>8/1 (1%)</td>
</tr>
<tr>
<td>Dry Eye</td>
<td>10/4 (1%)</td>
<td>3/1 (1%)</td>
</tr>
<tr>
<td>Vitreous Opacities</td>
<td>9/4 (1%)</td>
<td>8/1 (1%)</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>9/4 (1%)</td>
<td>5/5 (1%)</td>
</tr>
<tr>
<td>Posterior Capsule Opacification</td>
<td>8/1 (4%)</td>
<td>3/1 (1%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>8/1 (4%)</td>
<td>7/7 (7%)</td>
</tr>
<tr>
<td>Vitreous Hemorrhage</td>
<td>7/3 (3%)</td>
<td>4/1 (1%)</td>
</tr>
<tr>
<td>Foreign Body Sensation Injuries</td>
<td>6/3 (2%)</td>
<td>2/1 (1%)</td>
</tr>
<tr>
<td>Uveitis</td>
<td>6/3 (2%)</td>
<td>1/1 (1%)</td>
</tr>
<tr>
<td>Vitreous Nucleus</td>
<td>6/2 (3%)</td>
<td>5/1 (1%)</td>
</tr>
<tr>
<td>Eye Pain</td>
<td>6/1 (3%)</td>
<td>5/1 (1%)</td>
</tr>
<tr>
<td>Conjunctival Hemorrhage</td>
<td>5/1 (2%)</td>
<td>2/1 (1%)</td>
</tr>
<tr>
<td>Oral Cataract</td>
<td>3/1 (1%)</td>
<td>2/1 (1%)</td>
</tr>
<tr>
<td>Cataract in lens</td>
<td>3/1 (1%)</td>
<td>2/1 (1%)</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>3/1 (1%)</td>
<td>2/1 (1%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>4/1 (2%)</td>
<td>3/1 (1%)</td>
</tr>
<tr>
<td>Phacocystic Capsule Opacification</td>
<td>4/1 (2%)</td>
<td>3/1 (1%)</td>
</tr>
<tr>
<td>Ocular Hypertension</td>
<td>4/1 (2%)</td>
<td>3/1 (1%)</td>
</tr>
<tr>
<td>Vitreous Hemorrhage</td>
<td>3/1 (1%)</td>
<td>1/1 (1%)</td>
</tr>
<tr>
<td>Hypopyon</td>
<td>3/1 (1%)</td>
<td>1/1 (1%)</td>
</tr>
<tr>
<td>Glaucoma</td>
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<td>1/1 (1%)</td>
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</tr>
<tr>
<td>Vitreous Hemorrhage</td>
<td>3/1 (1%)</td>
<td>1/1 (1%)</td>
</tr>
</tbody>
</table>

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

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

HIGHLIGHTS OF PRESCRIBING INFORMATION

The following highlights contain information from other sections of this document.

*Indicates sections or subsections omitted from this document.

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. (1)

- Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for视神经损害, 视野缺损, 后部非感染性葡萄膜炎, and subsequent cataract surgery, elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, secondary vascular infection from pathogens including herpes simplex, and perforation of the globe when there is herniation of the cornea or sclera. (5.2)

- Adverse reactions associated with ophthalmic steroids including YUTIQ include cataract formation and perforation of the globe where there is thinning of the cornea or sclera. (5.2)

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Pregnancy/Lactation

8.7.6.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

8.11 DESCRIPTION

8.12 CLINICAL PHARMACOLOGY

8.13 CLINICAL TRIALS

8.14 CLINICAL STUDIES

8.15 HOW SUPPLIED/STORAGE AND HANDLING

8.16 PATIENT COUNSELING INFORMATION

8.17 ADVERSE REACTIONS

8.18 CONTRAINDICATIONS

8.19 WARNINGS AND PRECAUTIONS

8.20 CLINICAL STUDIES

8.21 CLINICAL PHARMACOLOGY

8.22 DESCRIPTION

8.23 DOSAGE AND ADMINISTRATION

8.24 PATIENT COUNSELING INFORMATION

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.

Sect.3 of this document contains information not listed.

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

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.

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

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

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视神经损害, 视野缺损, 后部非感染性葡萄膜炎, and perforation of the globe where there is thinning of the cornea or sclera. (2.3)

- The implant may migrate into the anterior chamber if the posterior lens capsule is not intact. (5.3)

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INSTRUCTIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

2.2 Administration

2.3 DOSAGE FORMS AND STRENGTHS

3 CONTRAINDICATIONS

4 WARNINGS AND PRECAUTIONS

5 ADVERSE REACTIONS

6 ADVERSE REACTIONS

7 ADVERSE REACTIONS

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10 ADVERSE REACTIONS

11 DOSAGE FORMS AND STRENGTHS

12 DOSAGE AND ADMINISTRATION

13 DISCUSSION

14 CLINICAL STUDIES

15 CLINICAL STUDIES

16 CLINICAL STUDIES

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.
8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Maternal systemic exposure to YUTIQ results in fetal exposure. Fetal and maternal corticosteroid exposures are similar after intravitreal and systemic administration. The corticosteroids are present in human milk after systemic administration, and may produce suppressive effects on infant growth and development. Animal reproduction studies have not been conducted with YUTIQ.

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

<table>
<thead>
<tr>
<th>Study</th>
<th>YUTIQ</th>
<th>Sham</th>
<th>Difference (95% CI) in recurrence rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>33</td>
<td>58% (40%, 70%)</td>
</tr>
<tr>
<td>2</td>
<td>22</td>
<td>28</td>
<td>27% (9%, 43%)</td>
</tr>
</tbody>
</table>

14. CLINICAL STUDIES

The efficacy of YUTIQ was assessed in two randomized (2:1, YUTIQ: sham-injection), multi-centre, double-blind, parallel-group 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 4: Time to First Recurrence of Uveitis (ITT; All Randomized Patients)

- **Figure 4:** Time to First Recurrence of Uveitis (ITT; All randomized subjects) Study 1
- **Figure 5:** Time to First Recurrence of Uveitis (ITT; All randomized subjects) Study 2

15. PATIENT COUNSELING INFORMATION

15.1 Stenlaid-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 IOP which may need to be managed with eye drops or surgery.

15.2 Intravitreal Injection-related Effects

Advise patients that the drug substance is a synthetic corticosteroid, fluocinolone acetonide.

15.3 Steroid-related Effects

Advise patients not to drive or use machines until this has been resolved.

15.4 Systemic Absorption

Advise patients to seek immediate care from an ophthalmologist.

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

16. HOW SUPPLIED/STORAGE AND HANDLING

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

NDC: 71878-136-01

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

Patients: Please refer to the individual product's package labeling for complete prescribing information.

NOTICE: Patented. EyePoint Pharmaceuticals US, Inc. Watertown, MA 02472 USA

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

Patented.