Yutiq (fluocinolone acetonide)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Yutiq
- **Generic name:** Fluocinolone acetonide
- **Pharmacological class:** Steroid
- **Strength and Formulation:** 0.18mg; implant for intravitreal injection
- **Manufacturer:** EyePoint Pharmaceuticals
- **How supplied:** Single-use applicator—1 (with needle)
- **Legal Classification:** Rx

Yutiq


NDC 71879-136-01
YUTIQ™
(fluocinolone acetonide intravitreal implant) 0.18 mg
Contains:
one sterile intravitreal implant in a SINGLE DOSE ONLY applicator with 25 gauge needle
Each implant contains:
Active: 0.18 mg fluocinolone acetonide
Inactive: polyimide tube; polyvinyl alcohol, silicone adhesive and water for injection. Do not use if inner pouch is damaged.
Dispose of the applicator safely in biohazard sharps container.
YUTIQ

Indication

- Chronic non-infectious posterior segment uveitis

Dosage & Administration

- Give by intravitreal injection
- See full labeling for administration

Considerations for Special Populations

- **Pregnancy:** No adequate data on developmental risk associated with use
- **Nursing mothers:** Consider benefits of breastfeeding with potential adverse effect on infant
- **Pediatric:** Not established
- **Elderly:** No age-related differences in safety or efficacy observed

Contraindications

- Ocular or periocular infections

Warnings/Precautions

- Monitor for increased **IOP** and **endophthalmitis**; may include check for perfusion of the optic nerve head immediately, tonometry within 30 mins, and biomicroscopy between 2–7 days post injection
- Risk of secondary **ocular infections** (eg, bacterial, fungal, viral)

Warnings/Precautions

- History of **ocular herpes simplex**: not recommended
- Risk of implant migration if absent or torn posterior capsule of the lens

Adverse Reactions

- Cataract development
- Increased intraocular pressure
- Injection-related effects (eg, endophthalmitis, eye inflammation, choroidal/retinal detachments)
- Glaucoma
- Others

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

Clinical Studies

- Yutiq was evaluated in 2 randomized, multicenter, double-masked, parallel-group studies that included patients with non-infectious uveitis affecting the posterior segment of the eye

Clinical Studies

- The **primary endpoint** was the proportion of patients who experienced a recurrence of uveitis in the study eye within 6 months of follow-up
  - Recurrence was also evaluated at 12 months

Clinical Studies

- **Recurrence** was defined as either deterioration in visual acuity, vitreous haze attributable to non-infectious uveitis or the need for rescue medications

Clinical Studies

- In Study 1, **18%** of patients in the Yutiq arm had a recurrence within 6 months vs **79%** of patients in the sham arm (difference 60%, 95% CI, 41%, 73%; *P* <.01)
- Recurrence within 12 months was seen in **28%** vs **86%** of patients in the Yutiq and sham arms, respectively (difference 58%, 95% CI, 40%, 70%)

Clinical Studies

- In Study 2, **22%** of patients in the Yutiq arm had a recurrence within 6 months vs **54%** of patients in the sham arm (difference 32%, 95% CI, 15%, 48%; *P* <.01)
- Recurrence within 12 months was seen in **33%** vs **60%** of patients in the Yutiq and sham arms, respectively (difference 27%, 95% CI, 9%, 43%)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/drug/yutiq/