Retisert
(fluocinolone acetonide intravitreal implant) 0.59 mg
STERILE

INDICATIONS AND USAGE
- Retisert is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye.

CONTRAINDICATIONS
- Retisert is contraindicated in patients with a history of herpes simplex keratitis (including epithelial herpes simplex keratitis, dendritic keratitis), vaccinia, and varicella, and also in active viral, bacterial, mycobacterial or fungal infection of the cornea and conjunctiva coincident with long-term use of corticosteroids.

WARNINGS AND PRECAUTIONS
- Cataract formation has been observed.
- Delayed wound healing and perforation of the globe where there is thinning of the sclera.
- Retisert is designed to release fluocinolone acetonide as a rectangular tablet.

DOSAGE FORMS AND STRENGTHS
- 0.59 mg fluocinolone acetonide intravitreal implant.

DOSAGE AND ADMINISTRATION
- Dosing Information
- Retisert is designed to release fluocinolone acetonide as a rectangular tablet.

1. INDICATIONS AND USAGE

2. DOSAGE AND ADMINISTRATION

2.1 Dosing Information

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3. DOSAGE FORMS AND STRENGTHS

- 0.59 mg fluocinolone acetonide intravitreal implant.
- Retisert is designed to release fluocinolone acetonide as a rectangular tablet.

4. ADVERSE REACTIONS
- Blurred vision, necrotizing retinopathy, retinal detachment, vitreous hemorrhage, vitreous loss, and visual field loss.

ADVERSE REACTIONS

- Retisert is a surgically implanted sustained-release, ophthalmic drug device designed to release fluocinolone acetonide at a nominal rate for up to 3 years.

CONTRAINDICATIONS

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have not been established.

8.4 Pediatric Use

or cause other untoward effects. Caution should be exercised when justifies the potential risk to the fetus.

There are no adequate and well-controlled studies in pregnant women. Fluocinolone acetonide caused abortions and malformations in a few surviving fetuses. and rabbits during gestation at a maternal toxic dose of 50 μg/kg/day fourth gestational week. When administered subcutaneously to rats dosage levels. Fluocinolone acetonide when administered subcutaneously

8.1 Pregnancy

(33%). Other non-ocular adverse events occurring in approximately 6.2 Clinical Trials Experience - Non-Ocular Events

diplopia, eye swelling, retinal detachment, photopsia, retinal blepharitis, corneal edema, iris adhesions, choroidal detachment,

 Conjunctival hyperemia, reduced visual acuity, glaucoma, conjunctival and require cataract surgery. IOP lowering medications to lower

Based on clinical trials with RETISERT, during the 3-year post-implantation period. Uveitis recurrence rates at 1, 2, and 3 year post-implantation occurred in approximately 50 - 90% of patients. Cataract surgery is indicated when vision loss due to a rapid increase in IOP or a small, hard, white cataract is noted in the implanted eye.

These events occurred in approximately 5 - 9% of patients in decreasing order of incidence were eye discharge, photophobia, Stenographer, corneal injury (in all tissues; chemical debridement), eyelashes, eye swelling, retinal detachment, vitreous, eyelid edema, macula edema and vocal dystonia.

6.2 Stable and non-reactive to freezing.

Store in the original container at 15° - 25°C (59° - 77°F). Protect from light and moisture.

Each RETISERT consists of a tablet containing 0.59 mg of the active ingredient, Fluocinolone acetonide, and the following inactive ingredients: microcrystalline cellulose, polyvinyl alcohol, and magnesium stearate.

Chemical Name: Pregna-1,4-diene-3,20-dione,6,9-difluoro-11,21-dihydroxy- 16,17-[(1-methyl-ethylidene)bis(oxy)],(6β,11β,16α,17α)

MANUFACTURER INFORMATION

Manufactured by: Marketed by:

Bausch & Lomb Incorporated Rochester, NY 14609

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Table 1: Uveitis Recurrence Rates

Table 2: Adverse Reactions Rates

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17 PATIENT COUNSELING INFORMATION

15.5 PRECAUTIONS

15.1 Pregnancy

15.8 Nursing Mothers

15.3 Carcinogenesis

In a study of patients who received the intravitreal implant, and had final visual acuity at 1 year (mean, 1 in 3) after treatment, visual acuity was significantly improved from baseline at 3 weeks post-implantation.

Following implantation of RETISERT, nearly all patients will experience an immediate and temporary decrease in visual acuity in the implanted eye which lasts for approximately one to two weeks post operatively.

Based on clinical trials with RETISERT, within 3 years post-implantation, approximately 25% of patients will require IOP lowering medications to control intraocular pressure and 3% of patients will require filtering procedures to control intraocular pressure. See 15.5 Clinical Trials.

Based on clinical trials with RETISERT, during the 3 year post-implantation period nearly all phakic eyes are expected to develop cataracts and require cataract surgery.

Table 2: Adverse Reactions Rates

Table 1: Uveitis Recurrence Rates

2 Years Post-implantation 11 (10.2) 16 (13.8) 34 Weeks Post-

2 Years Pre-implantation 58 (53.7) 46 (39.7)

34 Weeks Pre-

17 (15.2) 16 (13.8)

1 Test.

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