Multifocal choroiditis is a panuveitis that predominantly affects women between 20 and 60 years of age, with a median of 28 to 33 years of age.\textsuperscript{1,2} The disease has an unknown etiology, and it is categorized as a white dot syndrome due to its characteristic fundoscopic appearance. Patients with multifocal choroiditis often report blurred vision, floaters, an enlarged blind spot, and photopsias.\textsuperscript{1,2} The following case report describes a patient who presented with clinical findings of unilateral multifocal choroiditis and who, upon correct diagnosis, was treated with RETISERT (fluocinolone acetonide intravitreal implant) 0.59 mg for long-term inflammatory control.

**AT A GLANCE**

- Multifocal choroiditis is a chronic inflammatory condition that requires long-term control.
- An accurate diagnosis is essential to determining an optimal treatment course, and further evaluation may be required for a patient who is not responding to treatment.
- A proactive treatment approach that controls the inflammation is important for preserving vision.

**Indication**

RETISERT\textsuperscript{®} (fluocinolone acetonide intravitreal implant) 0.59 mg is a corticosteroid indicated for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

**Important Safety Information**

- Surgical placement of RETISERT\textsuperscript{®} (fluocinolone acetonide intravitreal implant) 0.59 mg is contraindicated in active viral, bacterial, mycobacterial or fungal infections of the eye.

Please see additional Important Safety Information throughout and full Prescribing Information for RETISERT\textsuperscript{®} on pages 5-8.
**DIAGNOSIS:** The patient had a previous medical history of hypertension, asthma, anemia, as well as cataract surgery with intraocular lens implantation. Fluorescent treponemal antibody absorption, tuberculosis, and Lyme disease tests were all negative, minimizing the possibility of infectious uveitis. Her results also revealed normal levels of serum angiotensin-converting enzyme, minimizing the possibility of sarcoid uveitis. Other clinical measurements included an anterior chamber cell score of 1+, a vitreous haze score of 2+, and BCVA of 20/40 in her left eye. Examination of the fundus revealed media opacity consistent with vitreous haze. Peripapillary atrophy, as well as focal yellow-white lesions in the macula, were also visible surrounding the optic nerve (Figure 1A). Fundus images of the retinal periphery indicated multiple areas of chorioretinal atrophy consistent with multifocal choroiditis (Figure 1B-1E). Fluorescein angiography of her left eye revealed optic disc staining and focal areas of hyperfluorescence within the macula and scattered throughout the posterior pole, suggestive of window defects in the retinal pigment epithelium (RPE) (Figure 2). Further examination with OCT revealed areas of hyperfluorescence indicative of vitreous cells and vitritis (Figure 3). Additionally, areas of atrophy were visible in the macula temporal to the fovea, and the areas of RPE atrophy were consistent with the multifocal choroiditis lesions (Figure 3). All clinical signs were suggestive of noninfectious posterior uveitis or panuveitis, and the patient was ultimately diagnosed with unilateral multifocal choroiditis due to the presence of yellow-white peripheral and posterior chorioretinal lesions, which are typical manifestations of the condition.

**Figure 1. Vitreous haze and chorioretinal atrophy consistent with multifocal choroiditis.** Blue arrow indicates yellow-white lesions in the macula (A). Green arrows indicate areas of chorioretinal atrophy in the retinal periphery (B-E).

**Figure 2. Areas of hyperfluorescence in the macula and posterior pole.** The green arrow indicates an area of hyperfluorescence within the macula. Blue arrows indicate areas of hyperfluorescence scattered throughout the posterior pole.

**Figure 3. Detection of vitreous cells and areas of macular and RPE atrophy.** The OCT cross section shows focal areas of hyperreflectivity in the vitreous (green arrow), macular atrophy temporal to the fovea (white arrow), and focal areas of disruption in the RPE indicative of atrophy (blue arrows).
WHY RETISERT? Multifocal choroiditis is generally a chronic condition. The chorioretinal lesions may result in cystoid macular edema and choroidal neovascularization, which both contribute to vision loss. Considering that the patient’s vision was still intact, aggressive treatment was critical to preserve her vision and help prevent future vision loss. The chronic nature of the condition warranted a treatment that offered long-term control. Systemic therapy is often prescribed for patients with bilateral multifocal choroiditis, but it may not be appropriate for patients with single-eye involvement and no other organ systems involved. Additionally, the patient was not interested in systemic immunosuppression due to concerns about side effects of systemic therapies, regular blood work requirements, and the length of treatment duration. The risk and benefits of RETISERT were reviewed with the patient, and she elected to receive a RETISERT implant in 2014.

FOLLOW-UP: The patient exhibited a temporary decline in vision during the first 4 weeks following implantation but her uveitis did not worsen. In the months following implantation, the patient’s posterior uveitis was considered inactive, and she did not require any topical steroid eye drops. Her BCVA was 20/30, her quality of vision improved, and she did not see any floaters. A fundus photograph taken 7 months following implantation revealed that the vitreous haze had resolved (Figure 4). Although the peripapillary atrophy and the chorioretinal lesions in the macula remained, no new lesions had formed since RETISERT implantation. OCT imaging revealed clearance of vitreous cells, as indicated by an absence of focal hyperreflective

Important Safety Information (cont’d)

- 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.
- As with any surgical procedure, there is risk involved. Potential complications accompanying intraocular surgery to place RETISERT® into the vitreous cavity may include, but are not limited to, the following: cataract formation, choroidal detachment, endophthalmitis, hypotony, increased intraocular pressure, exacerbation of intraocular inflammation, retinal detachment, vitreous hemorrhage, vitreous loss, and wound dehiscence.
- 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 four weeks post-operatively.

Please see additional Important Safety Information throughout and full Prescribing Information for RETISERT® on pages 5-8.

Retisert® (fluocinolone acetonide intravitreal implant) 0.59 mg
areas (Figure 5). Although the macular atrophy temporal to the fovea and RPE atrophy remained, no new lesions were observed after RETISERT implantation. Two years following implantation, the patient’s IOP had increased to 28 mm Hg. She began a combination therapy of brimonidine 0.2% and timolol 0.5% twice daily, and her IOP returned to the baseline measurement of 15 mm Hg.

**REIMPLANTATION:** RETISERT was designed to release fluocinolone acetonide locally to the posterior segment of the eye to deliver corticosteroid therapy for approximately 2.5 years where it is needed. The RETISERT implant may need to be replaced following depletion of fluocinolone acetonide. In 2017, the patient elected to receive a second RETISERT implant rather than risk having a flare recur. In the 18 months following the second RETISERT implantation, the patient’s ocular inflammation remained controlled, and her vision remained stable with a BCVA of 20/30. Her eye pain and photophobia had also improved. The patient’s IOP was maintained at an acceptable level using topical IOP-lowering medications.

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**Conclusions**

Multifocal choroiditis exhibits classical lesions that are typically 50- to 100-µm punched-out chorioretinal scars at the posterior pole. Patients with this condition also present with anterior segment cells, vitritis, and acute yellow-white chorioidal lesions of the macula. This disease typically manifests as a bilateral condition. The clinical appearance of this case aligned closely with the classical features of multifocal choroiditis, but it was atypical in that only one eye was involved. An accurate diagnosis was essential to determining that the patient required an aggressive treatment to help preserve her vision as well as provide long-term control of inflammation. In this patient, RETISERT delivered long-term control of inflammation and improved her vision with minimal complications.

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**Important Safety Information (cont’d)**

- Use of corticosteroids may result in elevated IOP and/or glaucoma. Based on clinical trials with RETISERT®, within 3 years post-implantation, approximately 77% of patients will require IOP lowering medications to control intraocular pressure and 37% of patients will require filtering procedures to control intraocular pressure.
- Patients should be advised to have ophthalmologic follow-up examinations of both eyes at appropriate intervals following implantation of RETISERT®. Physicians should periodically monitor the integrity of the implant by visual inspection.
- Ocular administration of corticosteroids has been associated with delayed wound healing and perforation of the globe where there is thinning of the sclera.
- The most frequently reported ocular adverse events in clinical trials with RETISERT® occurring in 50-90% of patients included: cataract, increased intraocular pressure, procedural complications and eye pain. The most common non-ocular event reported was headache (33%).

Please see additional Important Safety Information throughout and full Prescribing Information for RETISERT® on pages 5-8.

**References:**

8. RETISERT [prescribing information].

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Retisert®
(flucinolone acetonide intravitreal implant) 0.59 mg
STERILE

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RETISERT safely and effectively. See full prescribing information for RETISERT.

RETISERT (flucinolone acetonide intravitreal implant) 0.59 mg for intravitreal use
Initial U.S. Approval: 1963

------------------ INDICATIONS AND USAGE ------------------
RETISERT is a corticosteroid indicated for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye. (1)

------------------ DOSAGE AND ADMINISTRATION ------------------
• RETISERT is surgically implanted into the posterior segment of the affected eye through a pars plana incision. (2.1)
• RETISERT is designed to release flucinolone acetonide at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3-0.4 mcg/day over approximately 30 months. (2.1)
• Aseptic technique should be maintained at all times prior to and during the surgical implantation procedure. (2.2)

------------------ DOSAGE FORMS AND STRENGTHS ------------------
• 0.59 mg flucinolone acetonide intravitreal implant. (3)

------------------ CONTRAINDICATIONS ------------------
• Surgical placement of RETISERT is contraindicated in active viral, bacterial, mycobacterial and fungal infections of ocular structures. (4.1)

------------------ WARNINGS AND PRECAUTIONS ------------------
• Cataract formation: Nearly all phakic patients are expected to develop cataracts and require cataract surgery. (5.1)
• Endophthalmitis: Late onset endophthalmitis has been observed. (5.2)
• Increase in intraocular pressure: Use of corticosteroids may result in elevated IOP and/or glaucoma. (5.3) IOP lowering medications were required in > 75% of patients; filtering surgeries were required in > 35% of patients. (6.1)
• Separation of implant components: Physicians should periodically monitor the integrity of the implant by visual inspection. (5.4)

------------------ ADVERSE REACTIONS ------------------
• Ocular adverse events included procedural complications, and eye pain (> 50%). Thirty-five to forty percent of patients reported ocular/conjunctival hyperemia, reduced visual acuity, and conjunctival hemorrhage. (6.1)
• The most common non-ocular event reported was headache (33%). (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2017
FULL PRESCRIBING INFORMATION

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

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information
RETISERT (fluocinolone acetonide intravitreal implant) 0.59 mg is implanted into the posterior segment of the affected eye through a pars plana incision.

The implant contains one tablet of 0.59 mg of fluocinolone acetonide. RETISERT is designed to release fluocinolone acetonide at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3-0.4 mcg/day over approximately 30 months. Following depletion of fluocinolone acetonide as evidenced by recurrence of uveitis, RETISERT may be replaced.

2.2 Handling of Implant
Caution should be exercised in handling RETISERT in order to avoid damage to the implant, which may result in an increased rate of drug release from the implant. Thus, RETISERT should be handled only by the suture tab. Care should be taken during implantation and explantation to avoid sheer forces on the implant that could disengage the silicone cup reservoir (which contains a fluocinolone acetonide tablet) from the suture tab. Aseptic technique should be maintained at all times prior to and during the surgical implantation procedure.

RETISERT should not be resterilized by any method.

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

4 CONTRAINDICATIONS

4.1 Viral, Bacterial, Mycobacterial and Fungal Infections of Ocular Structures
Surgical placement of RETISERT is contraindicated in active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in active bacterial, mycobacterial or fungal infections of the eye.

5 WARNINGS AND PRECAUTIONS

5.1 Cataract Formation
Use of corticosteroids may result in posterior subcapsular cataract formation. 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.

5.2 Endophthalmitis and Surgical Complications
Late onset endophthalmitis has been observed. These events are often related to the integrity of the surgical wound site. Careful attention to assure tight closure of the scleral wound and the integrity of the overlying conjunctiva at the wound site is important.

Potential complications accompanying intraocular surgery to place RETISERT into the vitreous cavity may include, but are not limited to, the following: cataract formation, choroidal detachment, endophthalmitis, hypotony, increased intraocular pressure, exacerbation of intraocular inflammation, retinal detachment, vitreous hemorrhage, vitreous loss, and wound dehiscence.

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 four weeks post-operatively.

5.3 Increase in Intraocular Pressure
Prolonged use of corticosteroids may result in elevated IOP and/or glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Patients must be monitored for elevated IOP.

Based on clinical trials with RETISERT, within 3-years post-implantation, approximately 77% of patients will require IOP lowering medications to control intraocular pressure and 37% of patients will require filtering procedures to control intraocular pressure [see Adverse Reactions (6.1)].

5.4 Separation of Implant Components
In vitro stability studies show that the strength of the adhesive bond between the silicone cup reservoir and the suture tab is reduced with prolonged hydration, indicating a potential for the separation of these components. The suture tab composition is a silicone elastomer reinforced with a polyester mesh. Physicians should periodically monitor the integrity of the implant by visual inspection.

5.5 Other Corticosteroid Induced Adverse Reactions
RETISERT should be used with caution in patients with a history of a viral, bacterial, mycobacterial or fungal infection of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia and varicella. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections (bacterial, fungal, and viral). In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term application of steroids. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used.

Since resistance to infections is known to be reduced by corticosteroids, simultaneous bilateral implantation should not be carried out, in order to limit the potential for bilateral post-operative infection.

Ocular administration of corticosteroids has also been associated with delayed wound healing and perforation of the globe where there is thinning of the sclera.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience - Ocular Events
The available safety data includes exposure to RETISERT in patients with chronic non-infectious uveitis affecting the posterior segment in two multicenter controlled clinical trials. Patients were randomized to dosage regimens of 0.59 mg or 2.1 mg implants.

The most frequently reported ocular adverse events were cataract, increased intraocular pressure, procedural complication, and eye pain. These events occurred in approximately 50 - 90% of patients. Cataract includes aggravated cataract, and posterior capsular opacification. Procedural complications includes post-op complication, post-op wound complication, post-op wound site erythema, and wound dehiscence.
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. IOP lowering medications to lower intraocular pressure were required in approximately 77% of patients; filtering surgeries were required to control intraocular pressure in 37% of patients. Ocular adverse events occurring in approximately 10 - 40% of patients in decreasing order of incidence were ocular/conjunctival hyperemia, reduced visual acuity, glaucoma, conjunctival hemorrhage, blurred vision, abnormal sensation in the eye, eye irritation, maculopathy, vitreous floaters, hypertony, pruritus, ptosis, increased tearing, vitreous hemorrhage, dry eye, eyelid edema, macula edema and visual disturbance.

Ocular adverse events occurring in approximately 5 - 9% of patients in decreasing order of incidence were eye discharge, photophobia, blepharitis, corneal edema, iris adhesions, choroidal detachment, diplopia, eye swelling, retinal detachment, photopsia, retinal hemorrhage and hyphema.

6.2 Clinical Trials Experience - Non-Ocular Events

The most frequently reported non-ocular adverse event was headache (33%). Other non-ocular adverse events occurring in approximately 5-20% of patients in decreasing order of incidence were nasopharyngitis, arthralgia, sinusitis, dizziness, pyrexia, upper respiratory tract infection, influenza, vomiting, nausea, cough, back pain, limb pain, and rash.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

No adequate animal reproduction studies have been conducted with fluocinolone acetonide. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Fluocinolone acetonide when administered subcutaneously at a dose of 0.13 mg/kg/day (approximately 10,000 times the daily clinical dose of RETISERT), during days 6 to 18 of pregnancy in the rabbit, induced abortion at the end of the third and at the beginning of the fourth gestational week. When administered subcutaneously to rats and rabbits during gestation at a maternal toxic dose of 50 mcg/kg/day (approximately 4,000 times the clinical dose of RETISERT), fluocinolone acetonide caused abortions and malformations in a few surviving fetuses.

There are no adequate and well-controlled studies in pregnant women. RETISERT should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when RETISERT is implanted in a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

8.5 Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

RETISERT™ (fluocinolone acetonide intravitreal implant) 0.59 mg is a sterile implant designed to release fluocinolone acetonide locally to the posterior segment of the eye at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3-0.4 mcg/day over approximately 30 months. The drug substance is the synthetic corticosteroid fluocinolone acetonide, represented by the following structural formula:

```
C24H30F2O6 Mol. Wt. 452.50
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Chemical Name: Pregna-1,4-diene-3,20-dione,6,9-difluoro-11,21-dihydroxy-16,17-[(1-methyl-ethylidene)bis(oxy)](6â€²,11â€²,16â€²)-

Fluocinolone acetonide is a white crystalline powder, insoluble in water, and soluble in methanol. It has a melting point of 265-266°C.

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

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.

There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A₂ inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂. Corticosteroids are capable of producing a rise in intraocular pressure.

12.3 Pharmacokinetics

In a subset of patients who received the intravitreal implant, and had blood samples taken at various times (weeks 1, 4 and 34) after implantation, plasma levels of fluocinolone acetonide were below the limit of detection (0.2 ng/mL) at all times. Aqueous and vitreous humor samples were assayed for fluocinolone acetonide in a further subset of patients. While detectable concentrations of fluocinolone acetonide were seen throughout the observation interval (up to 34 months), the concentrations were highly variable, ranging from below the limit of detection (0.2 ng/mL) to 589 ng/mL.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed on RETISERT to evaluate the carcinogenic potential or the effect on fertility of fluocinolone acetonide.

Fluocinolone acetonide was not genotoxic in vitro in the Ames test, the mouse lymphoma TK assay, or in vivo in the mouse bone marrow micronucleus assay.
14 CLINICAL STUDIES
In two randomized, double-masked, multicenter controlled clinical trials, 224 patients with chronic (a one year or greater history) non-infectious uveitis affecting the posterior segment of one or both eyes were randomized to receive a 0.59 mg RETISERT. The primary efficacy endpoint in both trials was the rate of recurrence of uveitis affecting the posterior segment of the study eye in the 34 week pre-implantation period compared to the rate of recurrence in the 34 week post-implantation period. Uveitis recurrence rates at 1, 2, and 3 year post-implantation were also compared to the 34 week pre-implantation period.

Detailed results are shown in table 1 below:

Table 1: Uveitis Recurrence Rates

<table>
<thead>
<tr>
<th>TIME POINT</th>
<th>STUDY 1</th>
<th>STUDY 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=108</td>
<td>N=116</td>
</tr>
<tr>
<td>Uveitis Recurrence Rates1 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34 Weeks Pre-implantation</td>
<td>58 (53.7)</td>
<td>46 (39.7)</td>
</tr>
<tr>
<td>34 Weeks Post-implantation</td>
<td>2 (1.8)</td>
<td>15 (12.9)</td>
</tr>
<tr>
<td>1 Year Post-implantation</td>
<td>4 (3.7)</td>
<td>15 (12.9)</td>
</tr>
<tr>
<td>2 Years Post-implantation</td>
<td>11 (10.2)</td>
<td>16 (13.8)</td>
</tr>
<tr>
<td>3 Years Post-implantation</td>
<td>22 (20.4)</td>
<td>20 (17.2)</td>
</tr>
<tr>
<td>3 Years2 Post-implantation</td>
<td>33 (30.6)</td>
<td>28 (24.1)</td>
</tr>
</tbody>
</table>

1 Recurrence of uveitis for all post-implantation time points was compared to the 34 weeks pre-implantation time point.
2 p-value <0.01 from McNemar’s χ² test.
3 Results presented include imputed recurrences. Recurrences were imputed when a subject was not seen within 10 weeks of their final scheduled visit.

16 HOW SUPPLIED/STORAGE AND HANDLING
The implant consists of a tablet encased in a silicone elastomer cup containing a release orifice and a polyvinyl alcohol membrane positioned between the tablet and the orifice. The silicone elastomer cup assembly is attached to a silicone elastomer suture tab with silicone adhesive. Each RETISERT is approximately 3 mm x 2 mm x 5 mm.

Each implant is stored in a clear polycarbonate case within a foil pouch within a Tyvek peelable overwrap. Each packaged implant is provided in a carton which includes the package insert.

NDC 24208-416-01 0.59 mg 1 count

Storage: Store in the original container at 15°-25°C (59°-77°F). Protect from freezing.

17 PATIENT COUNSELING INFORMATION
Patients should be advised to have ophthalmologic follow-up examinations of both eyes at appropriate intervals following implantation of RETISERT.

As with any surgical procedure, there is risk involved. Potential complications accompanying intraocular surgery to place RETISERT into the vitreous cavity may include, but are not limited to, the following: cataract formation, choroidal detachment, temporary decreased visual acuity, endophthalmitis, hypotony, increased intraocular pressure, exacerbation of intraocular inflammation, retinal detachment, vitreous hemorrhage, vitreous loss, and wound dehiscence.

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 four weeks post-operatively.

Based on clinical trials with RETISERT, within 3 years post-implantation, approximately 77% of patients will require IOP lowering medications to control intraocular pressure and 37% of patients will require filtering procedures to control intraocular pressure [see Adverse Reactions (6.1)].

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.

Manufactured for:
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Bridgewater, NJ 08807 USA

Manufactured by:
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d/b/a Bausch & Lomb Ireland
Waterford, Ireland

U.S. Patent Numbers: 6,217,895 and 6,548,078

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