Sympathetic ophthalmia (SO) is a rare bilateral granulomatous panuveitis believed to be an autoimmune response following injury to one eye. The precedent ocular insult may be either accidental or surgical: The incidence of SO has been estimated to be between 0.2% and 1% following penetrating ocular injury and at 0.01% following intraocular surgery. The time to disease onset varies widely, but approximately 80% of patients are diagnosed within the first 3 months following injury. Patients commonly present with blurred vision in the sympathizing eye and may also experience pain, floaters, epiphora, or photophobia. Granulomatous or nongranulomatous inflammation of the anterior segment may develop; in the early stage, however, SO may present only in the posterior segment. In fluorescein angiography, multiple or diffuse leakage sites at the level of the retinal pigment epithelium are commonly observed, and staining of the optic nerve head is sometimes seen. OCT can reveal retinal edema, if present, and may be used to monitor therapeutic progress. While rare, SO is sight-threatening and requires early and aggressive treatment. In one retrospective study of 32 SO patients seen at the National Eye Institute Uveitis Clinic, 10 patients (31%) had an outcome VA of 20/200 or worse. This case study describes a patient with blindness-threatening SO. Being unable to tolerate systemic corticosteroid therapy and not being a candidate for immunomodulatory therapy, the patient was treated with RETISERT (fluocinolone acetonide intravitreal implant) 0.59 mg therapy for control of chronic inflammation involving the posterior uveal segment.

Case Report: Sympathetic Ophthalmia

BACKGROUND: A 53-year-old man with a history of chronic obstructive pulmonary disease (COPD) experienced a globe rupture in his right eye, which ultimately required enucleation. The patient subsequently developed inflammation in the left eye, which was suggestive of SO. To manage flares of panuveitis, the patient had been treated intermittently with oral prednisone but did not return for regular follow-ups because of his medical comorbidities.

Indication

RETISERT® (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® (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® on pages 5-7.

Bausch + Lomb
**DIAGNOSIS:** The patient’s left eye had a VA of 20/400 and an IOP of 29 mm Hg. Wide-field fundus photography demonstrated optic nerve cupping (Figure 1A). Extensive glaucomatous damage was evident through glaucoma hemifield testing (Figure 1B) and OCT analysis of the retinal nerve fiber layer (Figure 1C). The patient was diagnosed with advanced primary open-angle glaucoma (POAG).

Fluorescein angiography of the left eye revealed diffuse leakage along the retinal capillaries and enhancement of the left optic nerve, consistent with active SO (Figure 2). OCT of the left eye demonstrated macular puckering with no retinal edema (Figure 3). The patient underwent a number of laboratory tests, including rapid plasma reagin, interferon gamma release assay, and fluorescent treponemal antibody absorption, all of which yielded results negative for syphilis or tuberculosis, thus reducing the possibility for the associated infectious uveitides. Results from an enzyme-linked immunosorbent assay for antibodies against *Borrelia burgdorferi* were also negative, which reduced the possibility of infectious uveitis due to Lyme disease. Additionally, the patient tested negative for antibodies against *Bartonella henselae*, which reduced the possibility of inflammation arising from cat-scratch disease. Based on the findings from these tests and the history of globe rupture in the right eye, the patient was diagnosed with SO.

**TREATMENT:** To manage IOP elevation, the patient was given brimonidine tartrate, 0.2%, administered three times a day, as well as dorzolamide-timolol (dorzolamide hydrochloride, 2%, and timolol maleate, 0.5%), administered twice a day. For the inflammation, the patient received prednisone for use up to 80 mg per day. However, the patient would only follow-up when he experienced a flare of inflammation. While maintaining use of prednisone, he developed pneumonia and required hospitalization multiple times, which led to more missed clinic follow-ups.

**WHY RETISERT?** The patient was unable to tolerate the dose of prednisone. He was also not a candidate for immunomodulatory therapy because of his frequent hospitalizations from lung infections and his inability to attend follow-up visits. With a VA at 20/400, he was at risk of going blind. The patient needed a therapy that offered long-term control of inflammation. RETISERT is a viable alternative therapy for patients who are intolerant to systemic therapies such as prednisone.

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**Figure 1. Evidence of glaucoma.** Wide-field fundus photograph (A) showed cupping of the optic nerve. The finding of a glaucoma hemifield test (B) was outside normal limits. OCT analysis, as seen in quadrant and sector thickness charts (C), demonstrated thinning of the retinal nerve fiber layer.

**Figure 2. Fundus fluorescein angiogram.** Staining showed diffuse capillary leakage and optic nerve enhancement.
Figure 3. OCT scan. Imaging revealed mild macular puckering but no retinal edema.

Figure 4. Simultaneous implantation of glaucoma drainage valve and RETISERT. The glaucoma drainage valve was implanted first, as seen in placement of the valve plate (A). The RETISERT implant was then prepared by suturing through the hole in the anchoring strut (B). The RETISERT implant was inserted approximately 4 mm posterior to the limbus (C), and the scleral incision was closed (D). Finally, an optional scleral graft was placed over the RETISERT wound (E).

WHY RETISERT? (CONT’D)
RETISERT is designed to release fluocinolone acetonide locally over approximately 2.5 years. Although RETISERT can provide long-term control, it is associated with adverse events, including IOP elevation and cataract formation. Thus, RETISERT implantation in a patient with glaucoma should be approached with caution. The patient had POAG and was unable to tolerate prednisone therapy, and I recommended that he receive a glaucoma drainage valve and RETISERT implant simultaneously in his left eye (Figure 4).

FOLLOW-UP: In the immediate weeks after the surgery, the patient experienced a temporary decrease in visual acuity. The patient was tapered off prednisone therapy shortly after the procedure. In a follow-up approximately 3 months following the surgery, the patient had a VA of 20/60 and an IOP of 5 mm Hg. He was no longer receiving prednisone therapy or IOP-lowering ophthalmic solutions. The patient did not experience any flares of uveitic inflammation following the procedure. He also did not experience any adverse events related to cataract or IOP elevation over the 3 months following RETISERT implantation. Unfortunately, he passed away after the 3-month follow-up due to complications from pneumonia.

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 5-7.
Conclusions

This case study describes a patient diagnosed with SO, a rare, sight-threatening bilateral granulomatous panuveitis that manifests in the sympathizing eye following injury to the fellow eye.\textsuperscript{1,5,7} The patient’s injured eye was enucleated, but this did not prevent the onset of SO. COPD that developed into recurring pneumonia and led to multiple hospitalizations prevented successful treatment with prednisone and precluded candidacy for immunomodulatory therapy. The patient had a history of uveitic flares, had developed POAG, and was at risk of going blind. He received a RETISERT implant to treat the posterior segment inflammation caused by SO, along with a glaucoma drainage valve to control glaucomatous progression. The patient was tapered off of prednisone and at his 3-month follow-up had not experienced any flares of uveitic inflammation.

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 5–7.

**Retisert®**
(fluocinolone 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.

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

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**INDICATION AND USAGE**
RETISET is a corticosteroid indicated for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye. (1)

**DOSE 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 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. (2.1)
- Aseptic technique should be maintained at all times prior to and during the surgical implantation procedure. (2.2)

---

**DOSE FORMS AND STRENGTHS**
- 0.59 mg fluocinolone acetonide intravitreal implant. (3)

---

**ADVERSE REACTIONS**
- The most common non-ocular event reported was headache (33%). (6.2)
- Ocular adverse events included procedural complications, and eye pain (> 50%).

---

**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 Incorporated at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 05/2019

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2 DOSAGE AND ADMINISTRATION
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  2.2 Handling of Implant
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
  5.1 Cataract Formation
  5.2 Endophthalmitis and Surgical Complications
  5.3 Increase in Intraocular Pressure
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6 ADVERSE REACTIONS
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**FULL PRESCRIBING INFORMATION**
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RETISET is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

2 DOSAGE AND ADMINISTRATION
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RETISET (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 shear 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.

RETISET should not be resterilized by any method.

---

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- Ocular adverse events included procedural complications, and eye pain (> 50%).
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Revised: 05/2019

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See 17 for PATIENT COUNSELING INFORMATION.

Revised: 05/2019
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 intraocular pressure, procedural complication, and eye pain. These events occurred in 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 corneal/conjunctival hyperemia, reduced visual acuity, glaucoma, conjunctival hemorrhage, blurred vision, abnormal sensation in the eye, eye irritation, maculopathy, vitreous floaters, hypotony, pruritus, ptosis, increased tearing, vitreous hemorrhage, dry eye, eye lid edema, macular 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 abnormalities, conjunctival detachment, diplopia, eye swelling, retinal detachment, photopsis, 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:

\[ \text{C}_{29}\text{H}_{18}\text{F}_{3}\text{O}_{4} \]

Mol. Wt. 452.50

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

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 temporarily in blood samples, the surviving fetuses.

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 Rates</td>
<td>N (%)</td>
<td>N (%)</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 Years (^3) 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 \(\chi^2\) 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:
Bausch & Lomb Incorporated
Bridgewater, NJ 08807 USA

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

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