



OMIDRIA®

(phenylephrine and ketorolac
intraocular solution)

1% / 0.3%

Product Monograph

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ABBREVIATIONS

AAO: American Academy of Ophthalmology; AE: Adverse event; ASC: Ambulatory surgery center; ASCRS: American Society of Cataract and Refractive Surgery; ASP: Average Sales Price; BCVA: Best corrected visual acuity; BSS[®]: Balanced salt solution; CME: Cystoid macular edema; CMS: Centers for Medicare and Medicaid Services; FDA: Food and Drug Administration; FLACS: Femtosecond laser-assisted cataract surgery; GMP: Good Manufacturing Practices; HCPCS: Healthcare Common Procedure Coding System; HHS: US Department of Health & Human Services; HOPD: Hospital outpatient department; IFIS: Intraoperative floppy iris syndrome; IOL: Intraocular lens replacement; IOP: Intraocular pressure; IV: Intravenous; MAC: Medicare Administrative Contractor; NSAID: Nonsteroidal anti-inflammatory drug; OPSS: Outpatient Prospective Payment System; OR: Operating room; PA: Prior authorization; PED: Pupil-expansion device; RLE: Refractive lens exchange; SAE: Serious adverse event; TASS: Toxic anterior segment syndrome; UCVA: Uncorrected visual acuity; US: United States; VA: Veterans Affairs; VAS: Visual analog scale; VMT: Vitreomacular traction.

EXECUTIVE SUMMARY

OMIDRIA® (phenylephrine and ketorolac intraocular solution 1% / 0.3%) is a sterile solution indicated for addition to an ocular irrigating solution during cataract surgery or intraocular lens (IOL) replacement procedures to maintain pupil size by preventing intraoperative miosis and for reducing postoperative pain.¹

Age-related cataract is the most common cause of vision impairment in the United States (US) and worldwide. The prevalence is increasing as the overall age of the population increases.² It has been estimated that by the year 2050, there will be approximately 50 million Americans affected by cataracts.³

While cataract surgery and other IOL replacement procedures are common and relatively simple, they are not without risk of complications.^{4,5} Adequate pupil dilation is perhaps the most important factor in safe and efficient cataract surgery because the pupil represents the viewing portal to a surgeon's operative field.^{6,7} By convention, a pupil diameter of at least 6 mm is considered optimal for cataract or lens replacement surgery, and maintenance of dilation throughout the procedure reduces the risk of many ocular complications, including risk of capsule tear, vitreous loss, retained lens fragments, iris damage, and improper IOL placement during surgery.^{8,9}

Per the American Academy of Ophthalmology (AAO) Preferred Practice Pattern Guidelines for Cataract in the Adult Eye and the American Society of Cataract and Refractive Surgery (ASCRS) Refractive Cataract Surgery Subcommittee, effective preoperative mydriasis is important to help minimize risks that accompany a small pupil and intraoperative miosis.^{4,10} Mydriasis is typically achieved with preoperatively administered topical and/or intraoperative/intracameral administration of anticholinergic agents, sympathomimetic agents, or both.^{10,11} Preoperative and/or postoperative topical nonsteroidal anti-inflammatory drugs (NSAIDs) or steroids are also commonly prescribed to reduce inflammation, surgical pain, and the risk of cystoid macular edema.¹¹ Preoperative and/or intracameral topical NSAIDs have been shown to help maintain intraoperative pupil tone.¹¹ However, the therapeutic effect of preoperative topical agents may be reduced or eliminated during surgery as the irrigating solution washes the drug away from ocular tissues.¹² OMIDRIA is the only FDA-approved product for delivering an NSAID (ketorolac) with the irrigating solution intraoperatively to inhibit inflammation, helping to prevent surgically induced miosis and to reduce postoperative pain. In fact, the ASCRS Refractive Cataract Surgery Subcommittee published guidance on making cataract surgery safer and easier to maximize postoperative outcomes and patient satisfaction. In that article, the Subcommittee highlights that OMIDRIA “is proven to be safe and well tolerated” and, “compared to investigators’ existing standards (e.g., intracameral epinephrine), significantly reduced intraoperative complications (posterior capsule rupture, retained nuclear fragments, vitreous loss) 4-fold, decreased the need for pupil-expansion devices (e.g., Malyugin ring), shortened surgical times, maintained pupil diameter in femtosecond laser-assisted procedures, and/or improved postoperative visual acuity.”¹⁰

The features that make OMIDRIA a safe and effective clinical option for cataract surgery and IOL replacement procedures include the following:

Mechanism of Action¹

The two active pharmaceutical ingredients in OMIDRIA, phenylephrine and ketorolac, act to maintain pupil size by preventing intraoperative miosis. Postoperative pain is also reduced.

Ketorolac

Ketorolac is a non-steroidal anti-inflammatory that inhibits both COX-1 and COX-2, resulting in a decrease in tissue concentrations of prostaglandins to reduce pain due to surgical trauma.

By inhibiting prostaglandin synthesis secondary to ocular surgical insult or direct mechanical stimulation of the iris, ketorolac also prevents surgically induced miosis.

Phenylephrine

Phenylephrine is an α_1 -adrenergic receptor agonist and, in the eye, acts as a mydriatic agent by contracting the radial muscle of the iris.

- In a canine model, ketorolac concentrations 10 hours after intracameral administration of OMIDRIA indicated that COX-1 and COX-2 receptors were effectively inhibited in both the aqueous and vitreous (Figure 2).¹⁶

Figure 1. OMIDRIA Mechanism of Action¹³⁻¹⁵

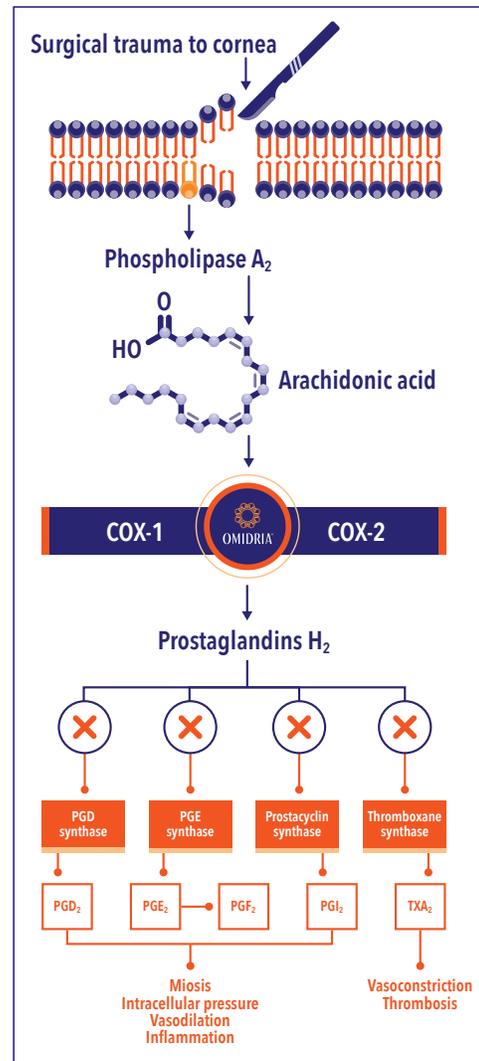
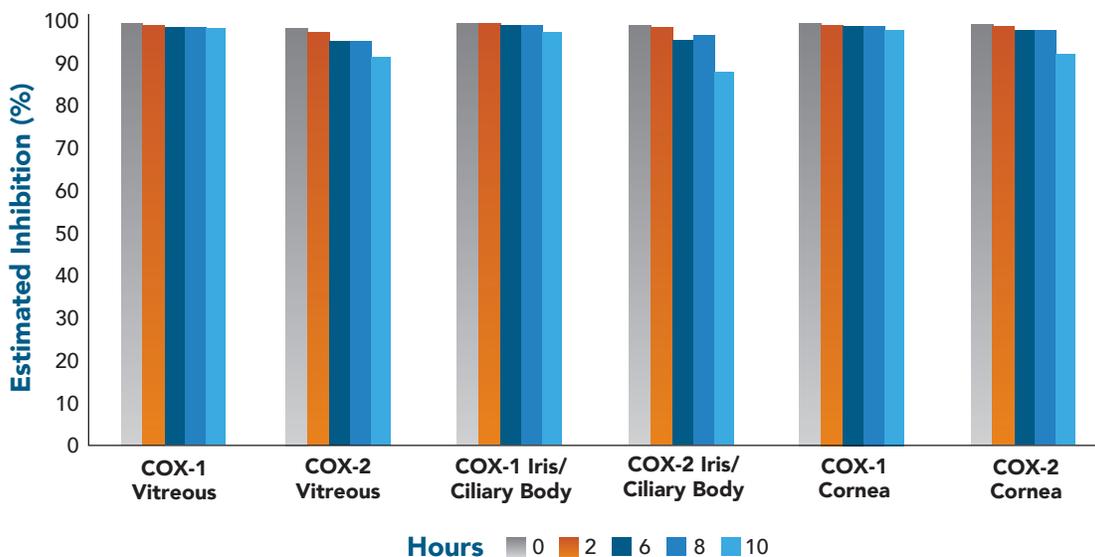


Figure 2. Estimated Retinal, Vitreous, Iris/Ciliary Body, and Cornea COX-1 and COX-2 Inhibition^{16,17}



Dr. Waterbury is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided financial support for this study.

Efficacy

- **OMIDRIA maintains mydriasis throughout the procedure.**
 - In a Phase 2b and two pivotal Phase 3 clinical trials, OMIDRIA was associated with significantly greater maintenance of pupil diameter during the procedure compared to placebo/vehicle ($p < 0.0001$).^{18,19}
 - In both pivotal Phase 3 clinical trials, only 4% of OMIDRIA-treated patients had pupil diameters < 6 mm at the time of lens implantation compared with 23% of patients who received placebo ($p < 0.0001$).¹⁹
 - Few patients in the OMIDRIA group (2.1%) had pupillary constriction ≥ 2.5 mm at any time during the procedure compared with 27.1% in the placebo group ($p < 0.0001$).¹⁹
- **OMIDRIA reduces postoperative pain.**
 - In the Phase 2b and Phase 3 clinical trials, the OMIDRIA group had less ocular pain during the first 10 to 12 hours after surgery, self-reporting significantly lower postoperative pain scores on a 100-mm visual analog scale (VAS; range: 0 = no pain to 100 = worst pain possible) compared with the placebo group across all time points ($p < 0.05$).^{18,19}
 - The OMIDRIA group had a significantly greater proportion of patients reporting no ocular pain (VAS = 0) at any time point during the first 10 to 12 hours after surgery compared with the placebo group (26% vs 17% [$p < 0.01$]).¹
 - Almost twice as many patients in the placebo group reported moderate-to-severe pain (VAS ≥ 40) at any time point compared with the OMIDRIA group (14.1% vs 7.2% [$p < 0.01$]).¹⁹
 - In addition to reporting less pain, fewer OMIDRIA-treated patients used pain medication on the day of surgery. One of the pain medications most commonly used by patients in the studies was fentanyl, an opioid, and only 24.6% of patients in the OMIDRIA group used any pain medication on the day of surgery compared with 35.1% in the placebo group ($p = 0.001$).¹⁹
- **Since introduction to the market, real-world studies have also shown that OMIDRIA improves additional outcomes important to surgeons and patients.**
 - Published and presented clinical studies report that in post-launch (i.e., not included in current labeling), prospective and retrospective, double-masked and open-label, cohort and case-controlled, single- and multi-center analyses, the use of OMIDRIA, compared to the surgeons' standard of care, statistically significantly:
 - Prevents intraoperative floppy iris syndrome (IFIS)²⁰
 - Reduces complication rates²¹ (epinephrine comparator)
 - Reduces postoperative cystoid macular edema (CME), breakthrough iritis, and pain²²
 - Decreases use of pupil-expansion devices (PEDs)^{21,23-26} (epinephrine comparator)
 - During surgery, OMIDRIA demonstrated a 50% reduction in VAS pain scores vs epinephrine¹³
 - Reduces surgical times^{21,24-26} (epinephrine comparator)
 - Prevents miosis during femtosecond laser-assisted surgery²⁶ (epinephrine comparator)
 - Improves uncorrected visual acuity on day after surgery²¹ (epinephrine comparator)
 - Delivers NSAID to the anterior chamber and related structures better than routine preoperative topical drug administration, resulting in effectively complete postoperative inhibition of COX-1 and COX-2^{12,16}

Safety

- **Overall, OMIDRIA was well tolerated by patients in clinical trials.**
 - The most common ocular adverse events (AEs) observed in $\geq 2\%$ of study patients receiving OMIDRIA were anterior chamber inflammation, increased intraocular pressure (IOP), posterior capsule opacification, eye irritation, and foreign body sensation.¹
 - Rates of AEs were similar between the OMIDRIA-treated patients and placebo-treated patients, with all adverse reactions being those expected with ocular surgery.¹⁹
- **OMIDRIA is contraindicated in:**
 - Patients who have known hypersensitivity to any of its ingredients.¹
- **OMIDRIA has warnings and precautions that include:**
 - Possibility of elevated blood pressure with systemic exposure to phenylephrine, one of the active ingredients in OMIDRIA.¹
 - Cross-sensitivity in patients with known hypersensitivities to acetylsalicylic acid, phenylacetic acid, or other NSAIDs.¹

Reliability

- **OMIDRIA is a sterile, FDA-approved product that is manufactured according to current Good Manufacturing Practices (cGMP).**
 - Once OMIDRIA is added to a standard ophthalmic irrigating solution, providers do not need to change their operating room routines.
 - OMIDRIA eliminates the need to use compounding pharmacies or to conduct compounding in the operating room (OR) to obtain the benefits of improved pupil dilation, prevention of miosis, and reduction of postoperative pain. Other intraoperative/intracameral products used for cataract or IOL replacement surgery are often compounded, off-label, and carry additional risk.^{19,27}
 - OMIDRIA is free of any preservatives and bisulfites, each of which is associated with toxic anterior segment syndrome (TASS).^{1,28}
 - FDA approval includes the FDA's review of manufacturing quality based on rigorous Good Manufacturing Practices (GMP).
 - Current compounded intraoperative products do not prevent prostaglandin-mediated miosis. OMIDRIA is the only NSAID-containing product approved by FDA for intraocular use. It is also the only FDA-approved product that inhibits prostaglandin release, blocking inflammation, both to maintain pupil size by preventing miosis and to reduce postoperative pain.¹
 - In addition, the U.S. Department of Health and Human Services (HHS) and the FDA recommend the use of an FDA-approved product when it is commercially available over the use of a compounded drug.²⁹⁻³¹

Reimbursement

OMIDRIA has a permanent J-code: J1097.³² Ambulatory surgical centers (ASCs) use this unique permanent HCPCS code to bill the Centers for Medicare & Medicaid Services (CMS) and other payers for separate payment. OMIDRIA used in cataract and lens replacement surgery for patients with Medicare Fee-for-Service coverage is separately paid (i.e., in addition to the facility fee) by CMS in the ASC setting.³³ CMS confirmed ongoing separate payment in ASCs in the Medicare Outpatient Prospective Payment System (OPPS) 2021 final rule.³⁴

DEMONSTRATED EFFICACY AND SAFETY

Evidence for the efficacy and/or safety and tolerability of OMIDRIA in cataract surgery or refractive lens exchange (RLE) was demonstrated in two pivotal Phase 3 clinical trials (referred to as Study 1 and Study 2) and a Phase 2b clinical trial.

An overview of the Phase 3 clinical trial designs is provided in Table 1 below.

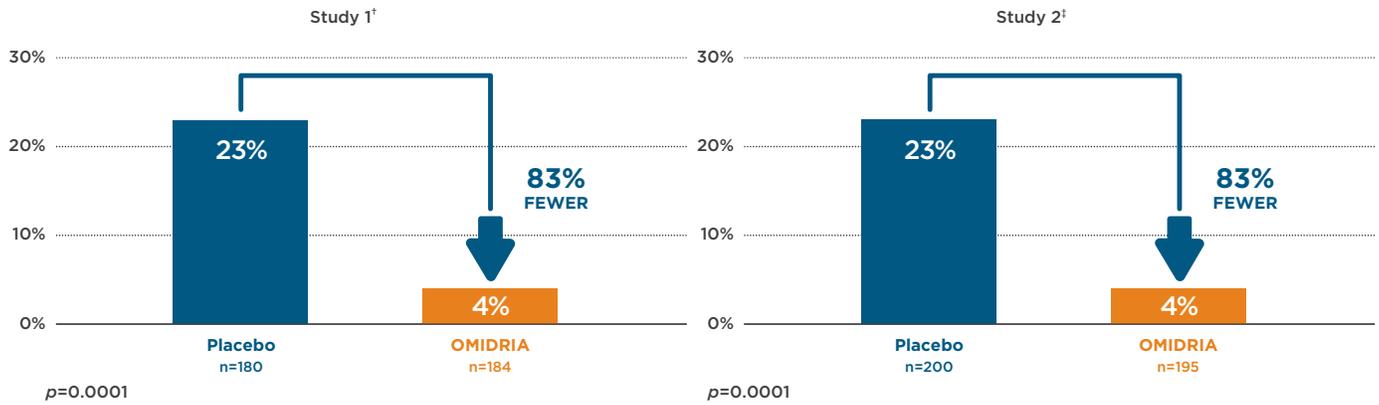
Table 1. Overview of OMIDRIA Phase 3 Clinical Trial Designs^{35,36}

| Study name | Study 1 | | Study 2 | |
|-------------------------------------|--|---------|--|---------|
| Country(ies) of conduct | US | | US and European | |
| Study design | Prospective, multicenter, randomized, double-masked, placebo-controlled | | | |
| Study population | Adults ≥ 18 years of age undergoing unilateral cataract surgery or RLE | | | |
| Duration of postoperative follow-up | Up to 14 days | | Up to 90 days | |
| Intraoperative treatments* | OMIDRIA | Placebo | OMIDRIA | Placebo |
| Number of patients | 201 | 201 | 202 | 204 |
| Number completing | 199 | 201 | 200 | 201 |
| Primary efficacy endpoint(s) | <ul style="list-style-type: none"> Intraoperative change in pupil diameter | | <ul style="list-style-type: none"> Intraoperative change in pupil diameter Ocular pain in the first 12 hours postoperatively | |
| Secondary efficacy endpoint(s) | <ul style="list-style-type: none"> Ocular pain in the first 12 hours postoperatively (100 mm visual analog scale [VAS]) Photophobia Inflammation Best corrected visual acuity (BCVA) | | <ul style="list-style-type: none"> % patients with a pupil diameter < 6 mm at lens implantation Postoperative ocular pain after the first 12 hours Photophobia Inflammation BCVA | |

*Both intraoperative treatments were diluted in balanced salt solution (BSS) and administered as irrigation solution during the procedure. All patients also received standard preoperative mydriatics, antibiotics, and anesthesia. On the day of surgery, fewer OMIDRIA-treated patients used postoperative pain medication, including opioids, than did the control group (24.6% vs 35.1%, respectively). Postoperatively, all patients continued antibiotics for 7 days. In Study 2, all patients also received topical ketorolac for at least 7 days after the first 24 hours postoperatively.

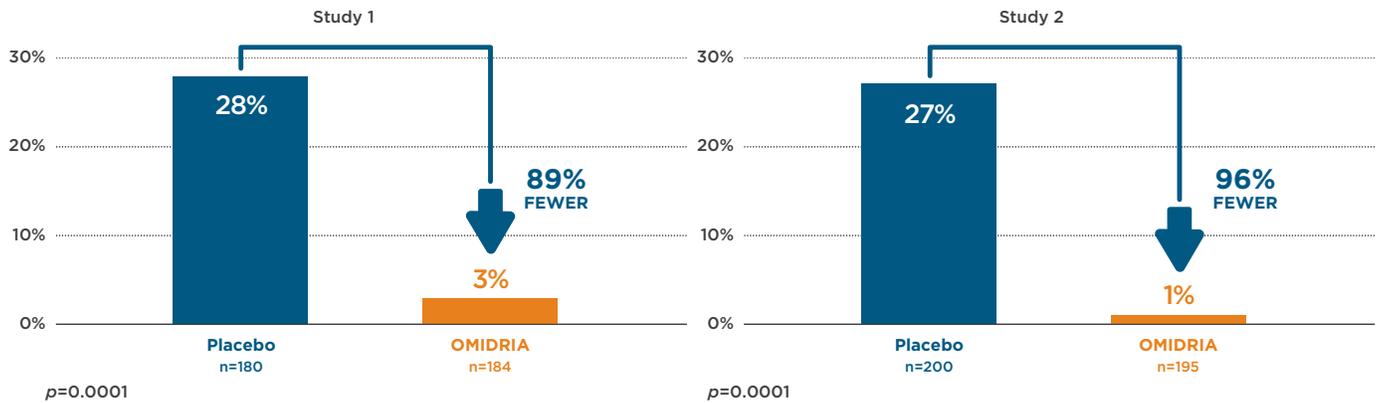
In both Phase 3 studies, OMIDRIA was significantly better than placebo in maintaining pupil diameter, preventing intraoperative miosis, and for reducing pain and use of pain medications, including opioids, during the early postoperative period following its addition to an irrigating solution and administration intracamerally during cataract surgery or RLE (Figures 3-5).^{35,36}

Figure 3. Proportion of Patients with a Pupil Diameter < 6 mm at the Start of Lens Implantation*^{35,36}



*All patients, including placebo-treated patients, received standardized preoperative mydriatics and anesthetics. [†]Post hoc analysis. [‡]Secondary endpoint.

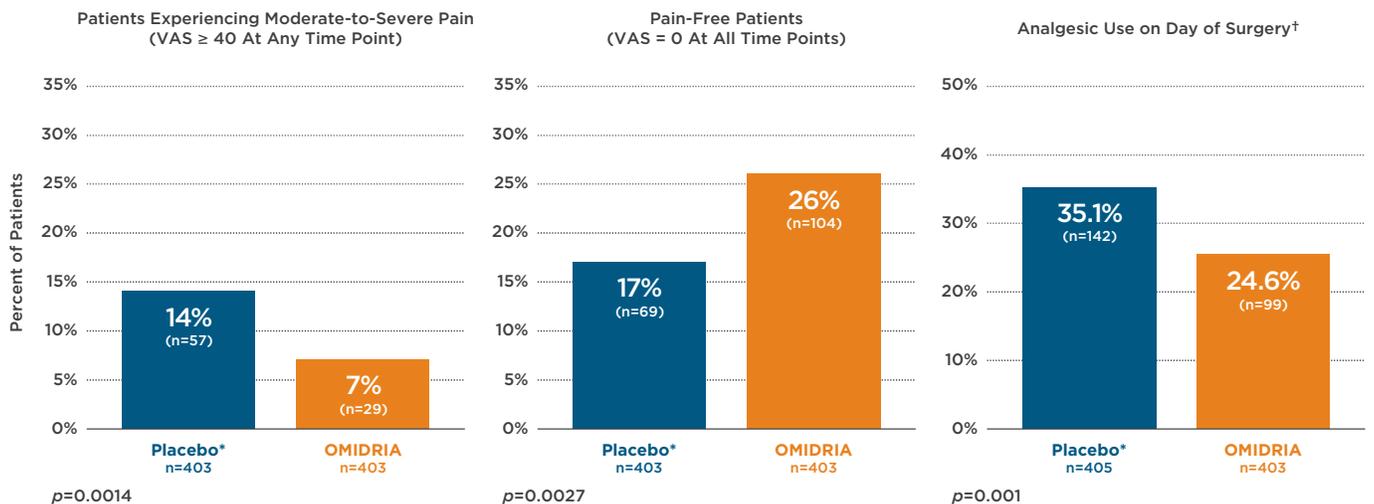
Figure 4. Proportion of Patients with a Decrease in Pupil Diameter ≥ 2.5 mm*^{†35,36}



*All patients, including placebo-treated patients, received standardized preoperative mydriatics and anesthetics. [†]Post hoc analysis.

A 2.5 mm reduction in pupil diameter can decrease the surgeon's operative field by >50%

Figure 5. Pooled Phase 3 (Study 1 & 2) Ocular Pain Outcomes*¹⁹



Pooled analysis of two multicenter, randomized, parallel-group, double-masked placebo controlled studies[‡]

*All patients, including placebo-treated patients, received standardized preoperative mydriatics and anesthetics. [†]All patients were allowed to take standardized analgesics including fentanyl (an opioid), for postoperative pain; the placebo group used significantly more analgesics on the day of surgery.

[‡]Post hoc analysis (Study 1) and secondary endpoint (Study 2).

Most commonly administered analgesics included fentanyl, an opioid

In the pivotal Phase 3 trials, OMIDRIA was well tolerated. Rates of treatment-emergent AEs were similar among patients receiving OMIDRIA or placebo (Table 2).¹⁹ The majority of AEs were mild to moderate in severity. Only one serious adverse event (SAE) and discontinuation due to an AE occurred in both studies. This event was a death due to a workplace accident (electrocution) that was deemed unrelated to study medication.¹⁹

Table 2. Pooled Phase 3 (Study 1 & 2) Adverse Events Occurring in ≥ 2% Patients Overall*¹⁹

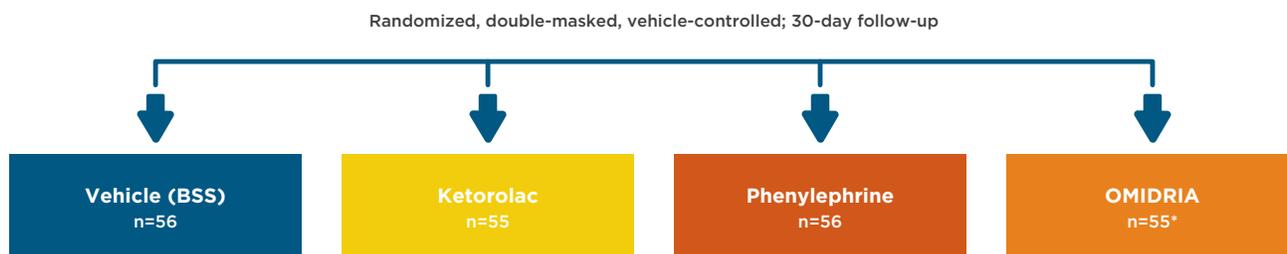
| | OMIDRIA (n=403) | Placebo (n=405) |
|---------------------------------|---------------------------|---------------------------|
| Any adverse event | 242 (60.0) | 271 (66.9) |
| Eye pain | 122 (30.3) | 162 (40.0) |
| Eye inflammation | 63 (15.6) | 62 (15.3) |
| Anterior chamber inflammation | 36 (8.9) | 34 (8.4) |
| Headache | 26 (6.5) | 38 (9.4) |
| Intraocular pressure increased | 19 (4.7) | 14 (3.5) |
| Posterior capsule opacification | 18 (4.5) | 15 (3.7) |
| Ocular discomfort | 12 (3.0) | 21 (5.2) |
| Photophobia | 12 (3.0) | 20 (4.9) |
| Corneal edema | 11 (2.7) | 12 (3.0) |
| Conjunctival hyperemia | 11 (2.7) | 10 (2.5) |
| Foreign body sensation in eye | 8 (2.0) | 10 (2.5) |
| Vision blurred | 5 (1.2) | 17 (4.2) |

*Post hoc analysis.

Phase 2b Clinical Study

The Phase 2b clinical trial provided supplementary evidence of safety and met the FDA's Combination Drug Policy requirements to show the independent effects of each active ingredient in OMIDRIA. This was a prospective, multicenter, randomized, double-masked, 4-arm, full-factorial, vehicle-controlled clinical trial with a maximum 30-day postoperative follow-up that was conducted in the US in adults ≥ 18 years of age undergoing unilateral cataract surgery (Figure 6).¹⁸

Figure 6. Phase 2b Clinical Study Design¹⁸



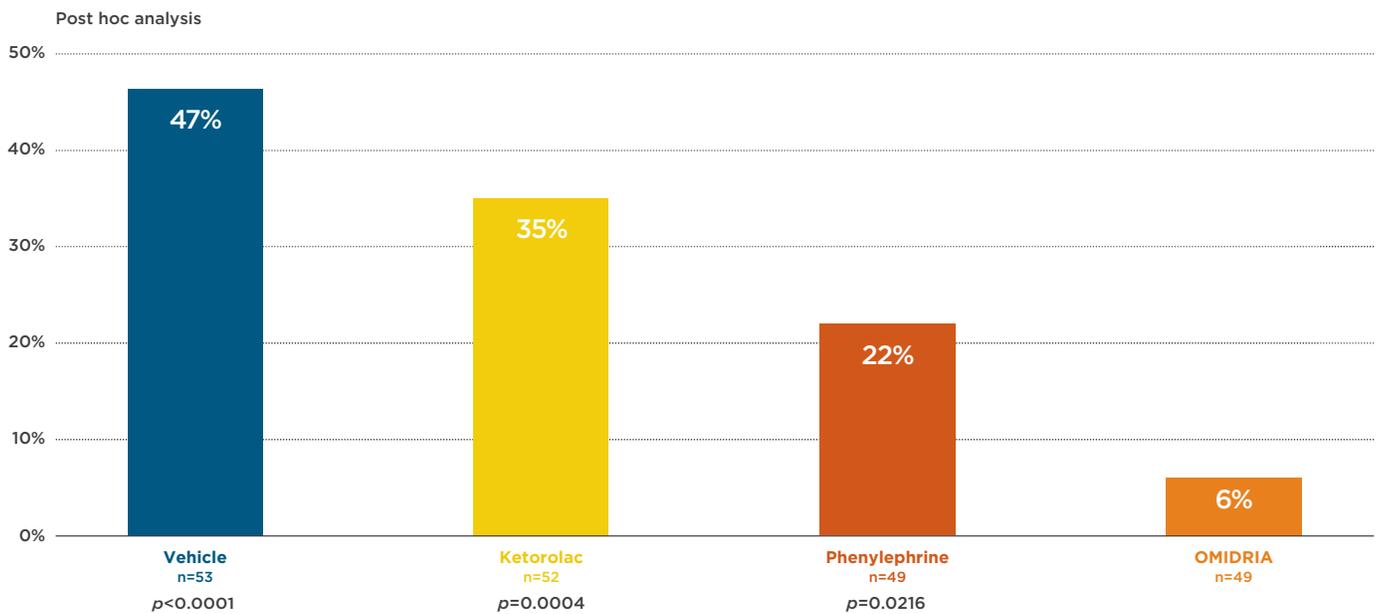
*One patient randomized, not treated.

All patients received standard preoperative topical = mydriatics: phenylephrine and tropicamide; anesthetics: lidocaine or tetracaine. Endpoints were met and statistically significant in favor of OMIDRIA.

Study medication was added to BSS and administered as irrigation solution during the procedure. All patients also received standard preoperative antibiotics, mydriatics, and anesthesia. After surgery, patients continued antibiotics for 7 days and were discharged with acetaminophen for pain control. The coprimary study endpoints were intraoperative change in pupil diameter and ocular pain by VAS during the first 12 hours after surgery.¹⁸

All patients except one who was randomized but withdrew consent before receiving treatment completed the study. OMIDRIA was found superior to both ketorolac and vehicle in maintaining mydriasis; it was associated with a significantly smaller mean change in pupil diameter during the procedure (both $p < 0.0001$).¹⁸ OMIDRIA was also shown to be superior to both phenylephrine ($p < 0.01$) and vehicle ($p < 0.05$) in reducing postoperative ocular pain during the first 10 to 12 hours after surgery.¹⁸ In a post hoc analysis, the proportion of patients with a pupil diameter < 6 mm at any time point during surgery was significantly less with OMIDRIA vs all comparators (Figure 7). The superiority of OMIDRIA over phenylephrine, which is an even more selective alpha-1-adrenergic agonist for mydriasis than is epinephrine, alone highlights the demonstrable and independent role of ketorolac in maintaining pupil diameter by preventing miosis during cataract surgery.¹⁸

Figure 7. Proportion of Patients with Pupil Diameter < 6 mm at Any Time During Surgery¹⁸



Post hoc analysis on Intent-to-Treat population.
All patients, including placebo-treated patients, received standardized preoperative mydriatics and anesthetics.

The majority of AEs were mild to moderate in severity.¹⁸ The most common ocular AEs (occurring in $\geq 5\%$ patients) with OMIDRIA were eye pain, eye inflammation, photophobia, and iritis.¹⁸ One patient in the phenylephrine group had an SAE (atypical facial neuralgia).¹⁸ There were no discontinuations due to AEs.¹⁸

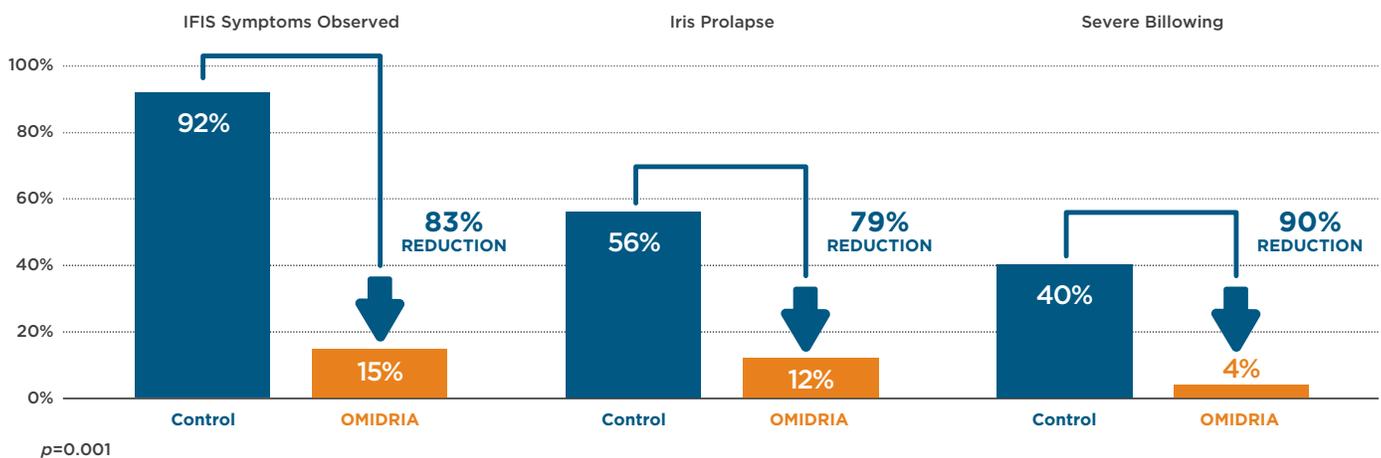
REAL-WORLD EVIDENCE (I.E., NOT INCLUDED IN CURRENT LABELING) OF IMPROVEMENT IN OUTCOMES IMPORTANT TO SURGEONS AND PATIENTS

Silverstein SM, Rana VK, Stephens R, et al. Effect of phenylephrine 1.0%–ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg.* 2018;44(9):1103-1108.

The effects of OMIDRIA on pupil diameter and IFIS symptoms were evaluated in cataract surgery patients at risk for IFIS (defined as any history of use of tamsulosin) in a prospective, randomized, double-masked, vehicle-controlled, single-surgeon, single-center study conducted in the US. Each group was comprised of 25 patients and 25 eyes.

Use of OMIDRIA prevented intraoperative miosis better and led to less IFIS symptoms compared to vehicle (iris prolapse [12.0% vs 56.0%, $p < 0.001$] and severe [stage 3] iris billowing [4.0% vs 40.0%, $p < 0.001$]) in tamsulosin-treated cataract surgery patients (Figure 8).

Figure 8. Effects of OMIDRIA on IFIS²⁰



Investigator-initiated, prospective, randomized, double-masked study in 50 male patients (50 eyes)*

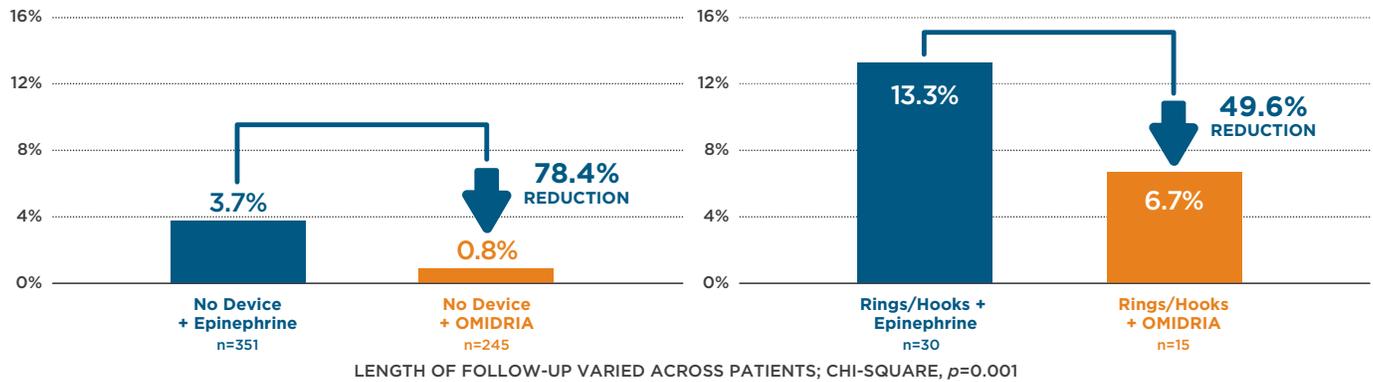
*Men with current or previous use of tamsulosin having unilateral cataract surgery via phacoemulsification with no other concurrent ophthalmic surgical procedure were included in the current study.
Dr. Silverstein is a consultant of Rayner Surgical Inc.

Rosenberg ED, Nattis AS, Alevi D, et al. Visual outcomes, efficacy, and surgical complications associated with intracameral phenylephrine 1.0%/ketorolac 0.3% administered during cataract surgery. *Clin Ophthalmol.* 2018;12:21-28.

Visual outcomes, surgical time, and perioperative surgical complications after intracameral use of OMIDRIA or epinephrine during cataract surgery were compared in a single-center, retrospective case review of 389 patients who underwent the procedure between August and November 2015 in a US surgical center. A total of 260 eyes were administered OMIDRIA and 381 eyes received epinephrine in the irrigating solution intraoperatively. All patients also received a preoperative topical NSAID and mydriatic.

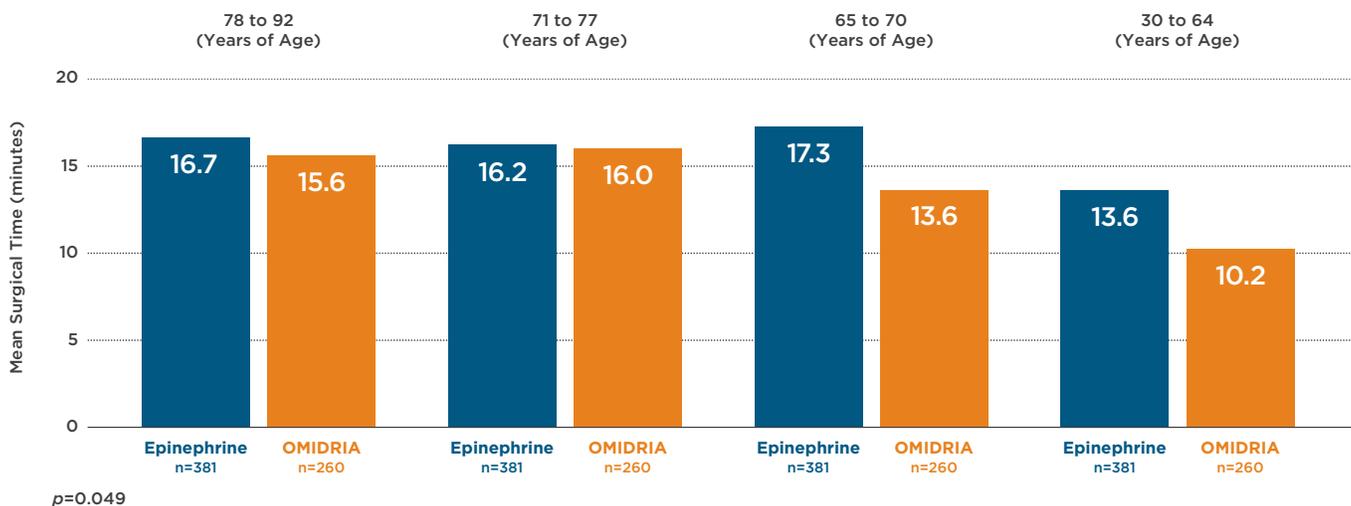
Results showed the OMIDRIA group had a statistically significant lower complication rate, a reduction in the need for pupil-expansion devices (PEDs), a shorter age-adjusted surgical time, and an improvement in postoperative Day 1 uncorrected visual acuity (UCVA) compared with the epinephrine group (Figures 9-10).

Figure 9. Complication Rates by Treatment Group*²¹



*Complications noted during this study include dislocated lens with intraocular lens exchange or repositioning, retained lens fragments, lens fragments in the vitreous, wound leakage, capsular tear (with or without anterior vitrectomy), macular puckering following surgery, and retinal detachment following surgery. Co-author E. Donnenfeld is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided financial support for this study.

Figure 10. Duration of Surgery by Age²¹

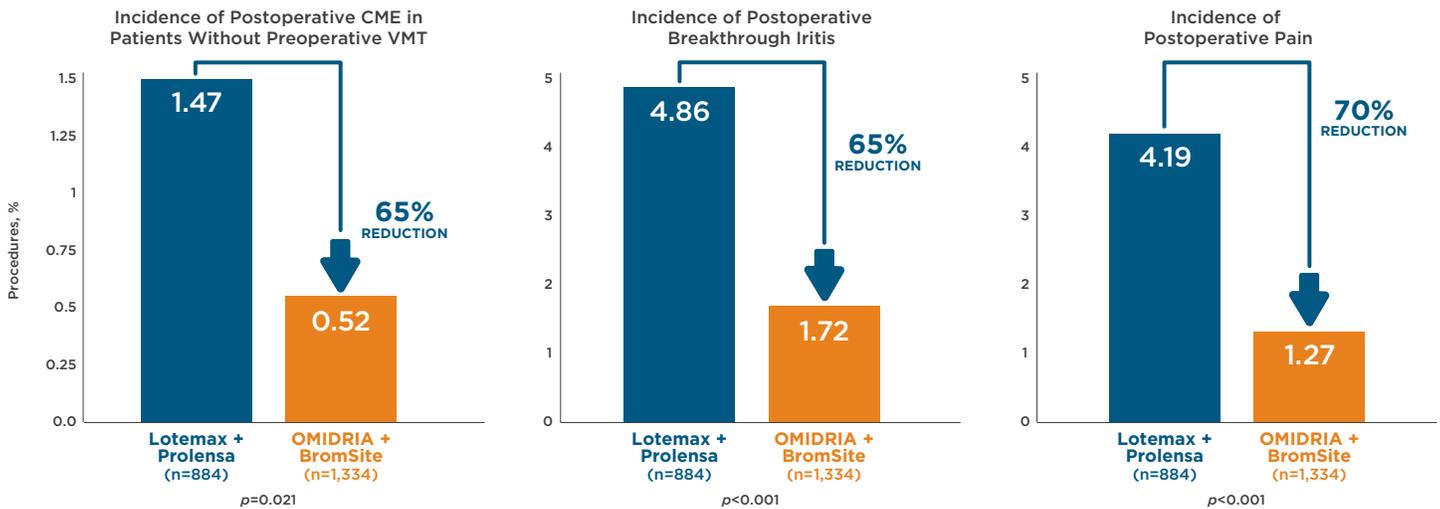


Co-author E. Donnenfeld is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided financial support for this study.

Visco DM, Bedi R. Effect of intracameral phenylephrine 1.0%-ketorolac 0.3% on postoperative cystoid macular edema, iritis, pain, and photophobia after cataract surgery. *J Cataract Refract Surg.* 2020;46(6):867-872.

In this retrospective, 2-cohort study (N=2218), consecutive cataract surgery patients at a single center received OMIDRIA (n=1334) or topical loteprednol (n=884). Study endpoints included incidence of postoperative inflammatory complications (CME and breakthrough iritis) and patient discomfort (pain and photophobia) at any point after postoperative day 1 through postoperative day 90 (Figure 11).

Figure 11. OMIDRIA + Topical NSAID Alone (No Steroid) Reduces CME, Breakthrough Iritis, and Pain Compared to a Postoperative Regimen of Steroid + NSAID (No OMIDRIA)²²



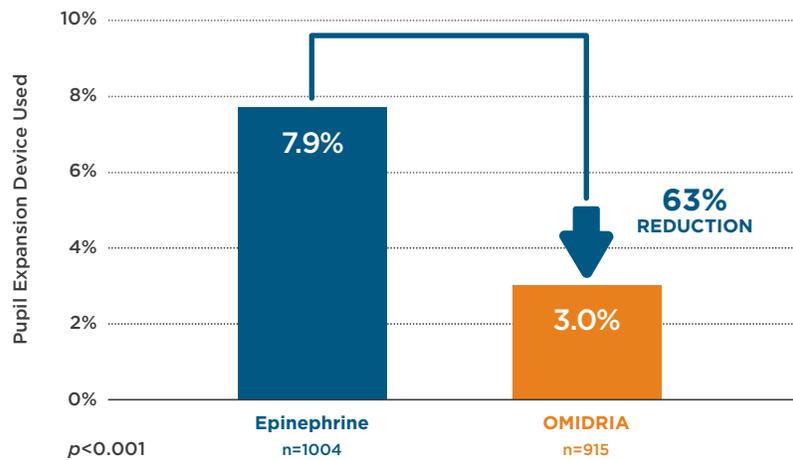
VMT: vitreomacular traction.
 Dr. Visco is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided financial support for this study.

Bucci FA Jr, Michalek B, Fluett AT. Comparison of the frequency of use of a pupil expansion device with and without an intracameral phenylephrine and ketorolac injection 1%/0.3% at the time of routine cataract surgery. *Clin Ophthalmol.* 2017;11:1039-1043.

Requirement for use of a PED (Malyugin Ring[®]) was evaluated in a single-center, retrospective, case-controlled analysis of cataract procedures performed by a single surgeon over two time periods (December 2013 to February 2015 and June 2015 to April 2016). The rate of PED use in a historical control group (December 2013 to February 2015) consisting of 1,004 consecutive cases that did not receive OMIDRIA intracamerally was compared with that of a treated group of 915 consecutive cases (June 2015 to April 2016) that received OMIDRIA intracamerally. Frequency of alpha-1 blocker and femtosecond laser use were also evaluated. Use of intraoperative epinephrine occurred in the historical control group per the surgeon’s judgment.

Overall frequency of PED use was significantly reduced in the OMIDRIA-treated group vs the historical control group ($p < 0.001$) (Figure 12). Femtosecond laser use was similar between the OMIDRIA group (16.3%) and the historical group (15.0%); however, 2.7% of the historical control group requiring femtosecond laser also required PED use compared with zero patients in the OMIDRIA group. Similarly, alpha-1 blocker use was not significantly different between the OMIDRIA group (5.7%) and the historical group (4.9%); however, PED use was required in 24.5% of patients on an alpha-1 blocker in the historical group compared with 12.7% of patients on an alpha-1 blocker in the OMIDRIA group ($p < 0.05$).

Figure 12. Overall Frequency of Pupil-Expansion Device Use²³



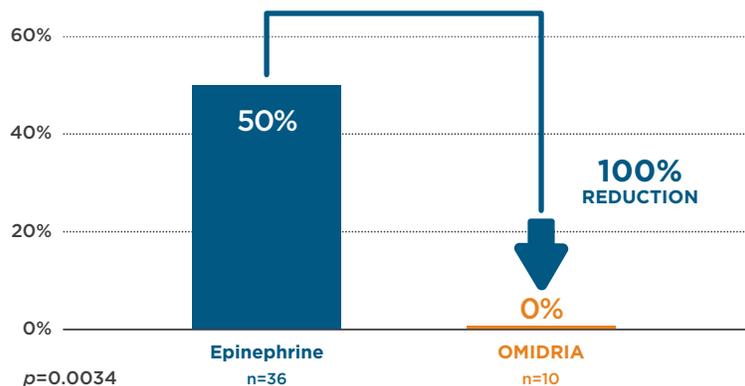
Dr. Bucci is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided financial support for this study.

Visco D. Effect of phenylephrine/ketorolac on iris fixation ring use and surgical times in patients at risk of intraoperative miosis. *Clin Ophthalmol.* 2018;12:301-305.

The effects of OMIDRIA on the use of PEDs and surgical time were evaluated in a US single-center, retrospective, case-controlled analysis of 46 patients that were preoperatively identified at risk for intraoperative miosis (defined as presurgical pupil diameter \leq 5 mm or a history of IFIS during surgery in the fellow eye) who underwent cataract surgery performed by the same surgeon. All patients received a preoperative topical NSAID and mydriatics and, based on insurance coverage, either OMIDRIA or epinephrine in irrigation solution intraoperatively.

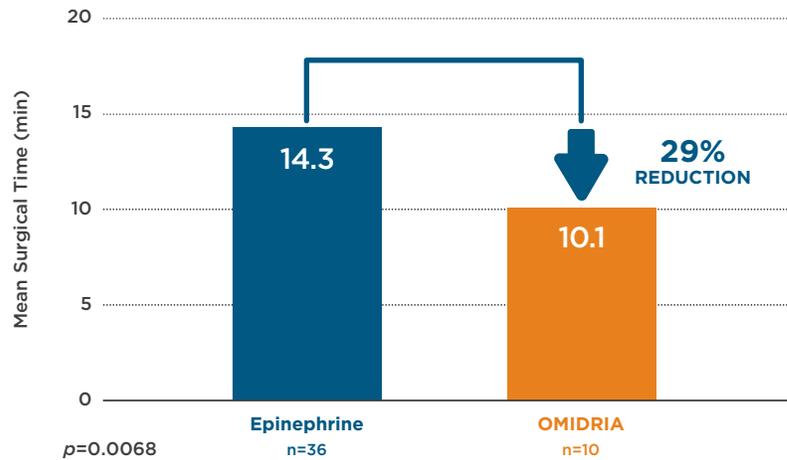
The results showed use of OMIDRIA in patients at risk for intraoperative miosis during cataract surgery was associated with less use of PEDs ($p = 0.0034$) and shorter surgical time ($p = 0.0068$) (Figures 13-14).

Figure 13. Frequency of Pupil-Expansion Device Use in Patients at Risk for Intraoperative Miosis²⁴



Retrospective case-controlled analysis of 46 patients at risk for requiring a pupil expansion device.
Dr. Visco is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided medical writing support for this study.

Figure 14. Mean Surgical Time in Patients at Risk for Intraoperative Miosis²⁴

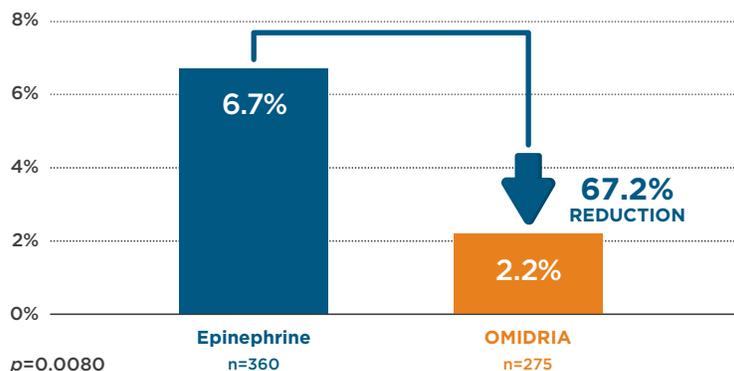


Retrospective case-controlled analysis of 46 patients at risk for requiring a pupil expansion device. Dr. Visco is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided medical writing support for this study.

Matossian C. Clinical and economic outcomes in cataract surgery using phenylephrine 1.0%-ketorolac 0.3% in a real-world setting. Presented at: ASCRS ASOA Annual Meeting 2018; April 13-17, 2018; Washington, DC.

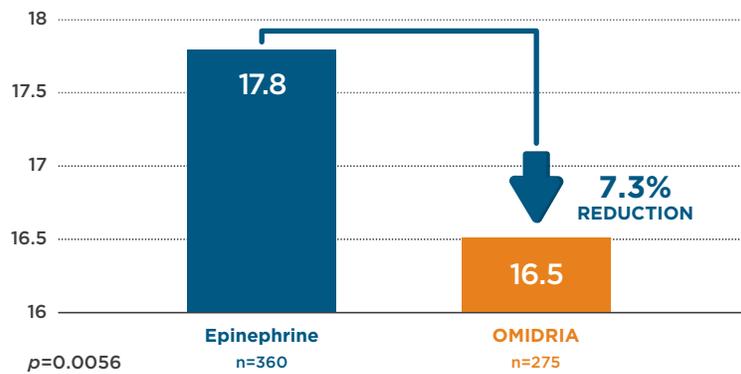
The effects of OMIDRIA on PED use and surgical time were evaluated in a retrospective case review of 375 cataract surgery patients who underwent the procedure and received either OMIDRIA (n=275 eyes) or epinephrine (n=360 eyes) in irrigation solution intraoperatively. The procedures occurred between March 2015 and December 2016 at one of two clinics by a single surgeon practicing at both locations. Results showed less PED use (2.2% vs 6.7%, p = 0.0080) and shorter surgical time (16.5 vs 17.8 minutes, p = 0.0056) in the OMIDRIA group compared with the epinephrine group (Figures 15-16). AEs were rare and mild, including transiently increased IOP (n=4) and mild iritis (n=1), all in the OMIDRIA group.

Figure 15. Frequency of Pupil-Expansion Device Use²⁵



Two-center, single-surgeon, retrospective case review. Dr. Matossian is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided medical writing support for this abstract.

Figure 16. Mean Surgical Time²⁵



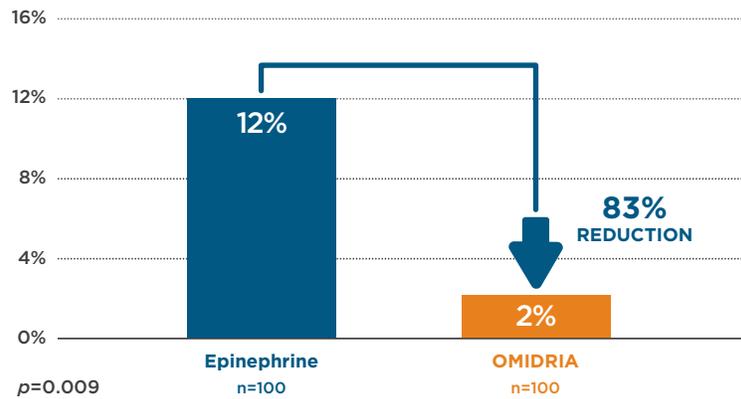
Two-center, single-surgeon, retrospective case review.
Dr. Matossian is a consultant of Rayner Surgical Inc. Rayner Surgical Inc. provided medical writing support for this abstract.

Walter K, Delwadia N, Coben J. Continuous intracameral phenylephrine-ketorolac irrigation for miosis prevention in femtosecond laser-assisted cataract surgery: reduction in surgical time and iris manipulation. *J Cataract Refract Surg.* 2019;45(4):465-469.

PED use and duration of surgery were evaluated in another retrospective analysis of 100 consecutive femtosecond cataract surgery cases using epinephrine in the intraoperative irrigating solution, followed by another 100 consecutive femtosecond cataract surgery cases in which OMIDRIA was used in the irrigating solution. All patients also received the same preoperative topical NSAID and all procedures were performed by a single surgeon using the same laser and under the same operative conditions.

Baseline characteristics, including starting pupil diameter (average 7.1 mm for both groups), were similar between the two groups. There was less requirement for use of a PED in the OMIDRIA group compared with the epinephrine group (2% vs 12%, $p = 0.009$). Duration of surgery was also shorter in the OMIDRIA group compared with the epinephrine group (8.1 vs 9.4 minutes, $p = 0.007$); even after excluding the cases that required PED use (8.1 vs 9.0 minutes, $p = 0.03$).

Figure 17. Frequency of Pupil-Expansion Device Use in Patients Undergoing FLACS²⁶

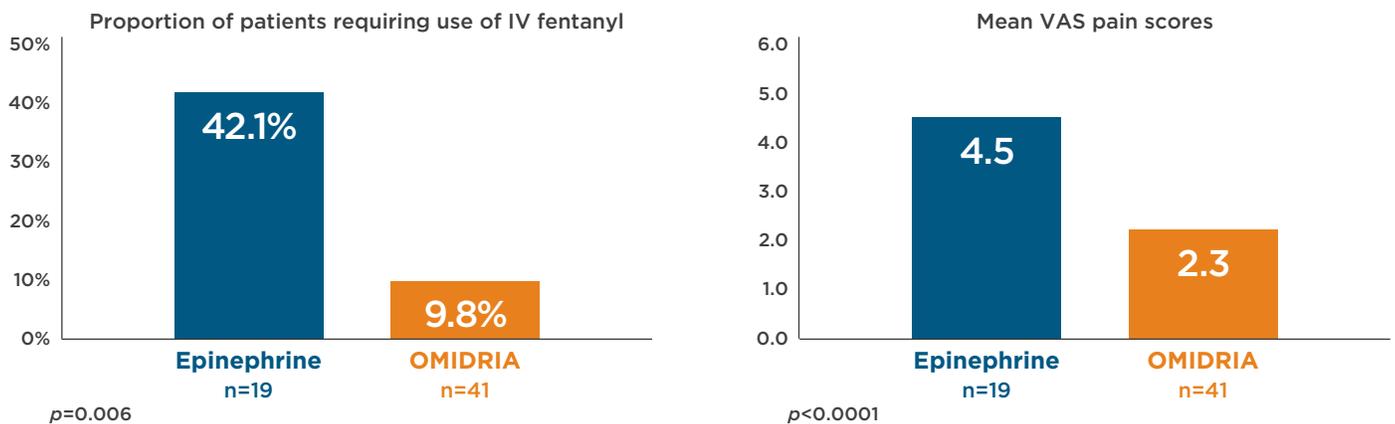


Retrospective case review analysis of patients undergoing femtosecond laser-assisted cataract surgery. Dr. Walter is a consultant of Rayner Surgical Inc.

Donnenfeld ED, Shojaei RD. Effect of intracameral phenylephrine and ketorolac 1.0%/0.3% on intraoperative pain and opioid use during cataract surgery. *Clin Ophthalmol.* 2019;13:2143-2150.

In a prospective, single-masked, comparative study, 60 patients at a single center underwent femtosecond laser-assisted cataract surgery or conventional phacoemulsification under topical lidocaine gel anesthesia and intracameral preservative-free lidocaine 1%. Eligible participants were prospectively assigned to receive either intracameral phenylephrine and ketorolac 1.0%/0.3% or intracameral epinephrine. Intravenous (IV) fentanyl was administered for ocular discomfort in patients who complained of intraoperative pain. Outcome measures included both pain, measured by mean VAS pain scores from 0 (no pain) to 10 (extreme pain), and the use of IV fentanyl during surgery. A composite endpoint identified a “responder” as a patient who (1) did not require fentanyl during surgery and (2) experienced no pain to mild pain (VAS score ≤ 3).

Figure 18. Need for Opioids (i.e., Fentanyl) During Surgery and Mean VAS Pain Scores¹³



VAS scale of 0-10. Dr. Donnenfeld is a consultant of Rayner Surgical Inc.

REIMBURSEMENT FOR OMIDRIA

Medicare Part B

OMIDRIA used in cataract and lens replacement surgery for patients with Medicare Fee-for-Service coverage is separately paid (i.e., in addition to the facility fee) by CMS in the ASC setting.³³ CMS confirmed ongoing separate payment in ASCs in the Medicare OPPS 2024 final rule.³⁴ CMS has now added a section to the ASC payment system regulation to clearly and firmly establish its policy to pay separately for nonopioid pain-management surgical drugs when used in the ASC setting.³⁷

Specifically, beginning on or after January 1, 2022, a nonopioid drug that functions as a surgical supply is eligible for separate payment in the ASC setting if CMS determines that the drug has 1) an FDA-approved indication for pain management or analgesia and 2) a per-day cost that exceeds the drug packaging threshold (\$135 for CY 2024) set annually through CMS's rule-making process. After January 1, 2023, the following were added to eligibility: 3) the drug or biological does not have transitional pass-through payment status, and 4) the drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than 416.174. CMS specifically evaluated OMIDRIA in the rule and concluded that OMIDRIA meets the criteria and should receive separate payment under the ASC payment system for CY 2024.³⁷

Passage of the Consolidated Appropriations Act 2023 has secured separate payment status in ASCs for OMIDRIA through January 1, 2028. HOPD separate payment status is secured for OMIDRIA starting January 1, 2025, through January 1, 2028.*

For OMIDRIA reimbursement in the ASC setting, CMS sets the payment rate at ASP plus 6%, minus a set amount due to sequestration.³⁸ OMIDRIA now has separate payment status in ASCs through January 1, 2028. Approximately 83% of Medicare Fee-for-Service patients have some form of supplemental insurance, which covers co-pays.⁴⁰

Veterans Health Administration

OMIDRIA was also added to the VA National Formulary in April 2018 following a thorough review of the drug's efficacy and safety data, including publications in peer-reviewed journals. By its inclusion on the VA National Formulary, OMIDRIA must be made available at all VA facilities nationwide that perform ophthalmic surgery. OMIDRIA is on the VA National Formulary with no PA required.

Other

- OMIDRIA is available on the Federal Supply Schedule.
- OMIDRIA has 340B pricing.

Reimbursement Support

Rayner offers the OMIDRIAssure® Program that provides comprehensive reimbursement services including:

- We Pay the Difference patient reimbursement program† for commercial insurance
- Equal Access patient assistance program for government-insured or uninsured patients, based on financial need
- Dedicated team of Field Reimbursement Managers to help you navigate through the reimbursement pathway

For more information, talk to your OMIDRIA representative or Rayner Field Reimbursement Manager, call 1-844-RAYNER1 (1-844-729-6371), or email omidriafrms@rayner.com.

Please see full terms and conditions for Reimbursement Support programs at <https://www.omidriahcp.com/access-and-support/>

*Section 4135(b) CAA provides for both a transitional period (December 29, 2022, to December 31, 2024) and a specified period (January 1, 2025, to January 1, 2028) during which nonopioid pain management drugs, such as OMIDRIA, will qualify for separate payment in the ASC setting.
†OMIDRIAssure program services are subject to change without notice. The We Pay the Difference Program patient benefit is not available for patients with any government insurance. Facility acquisition cost is determined after application of any volume-based discount. Claims must be submitted within 6 months of date of surgery. Rayner does not guarantee coverage or reimbursement. To be eligible for the Equal Access Patient Assistance Program, patients must be enrolled prior to surgery. For any patient eligible for the Equal Access Patient Assistance Program, (1) the facility receives a free vial of OMIDRIA prior to surgery, and (2) the patient's insurance carrier(s) should not be billed for OMIDRIA.

CONCLUSION

Clinical Benefits of OMIDRIA

Intraoperative use of OMIDRIA provides surgeons and patients with a medication for cataract surgery and other IOL replacement procedures, including refractive lens exchange, that:

- Inhibits the release of prostaglandins, blocking inflammation, to prevent miosis and effectively maintain pupil dilation.¹
- Provides greater pupil stability for better visualization of the operative field, which can lead to reduced surgical time and reduced use of PEDs.^{1,21,23-26}
- Results in fewer postoperative complications, such as IFIS, CME, and breakthrough iritis.^{20,22}
- Reduces pain as well as opioid use both during and after surgery.^{1,13,19}
- Improves patient experience with less pain, greater visual acuity, and fewer drops.^{1,21,22}
- Is manufactured according to FDA Good Manufacturing Practices, minimizing potential safety and liability risks associated with compounded products.
 - HHS and the FDA recommend the use of an FDA-approved product when it is commercially available over the use of a compounded drug.²⁹⁻³¹

Access and Reimbursement for OMIDRIA

- OMIDRIA has a unique permanent J-code: J1097.³²
- Non-opioid OMIDRIA qualifies for separate payment by CMS when used in ASCs.³⁴
- OMIDRIA now has separate payment status in ASCs through January 1, 2028.
- Rayner provides the OMIDRIAssure program, offering patients options to assist with the cost of OMIDRIA as well as dedicated access to comprehensive reimbursement programs for cataract procedures.

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Omidria® safely and effectively. See full prescribing information for Omidria.

Omidria® (phenylephrine and ketorolac intraocular solution) 1% / 0.3%, for addition to ocular irrigating solution
Initial U.S. Approval: 2014

INDICATIONS AND USAGE

Omidria is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for:

- Maintaining pupil size by preventing intraoperative miosis (1)
- Reducing postoperative pain (1)

Omidria is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement.

DOSAGE AND ADMINISTRATION

- Each vial of Omidria must be diluted prior to use for administration to a single patient undergoing cataract surgery or intraocular lens replacement.
- Dilute 4 mL of Omidria in 500 mL of ocular irrigating solution. Irrigation solution is to be used as needed for the surgical procedure. (2)

DOSAGE FORMS AND STRENGTHS

Intraocular solution containing phenylephrine 10.16 mg/mL (1%) and ketorolac 2.88 mg/mL (0.3%) for use in a single patient. (3)

CONTRAINDICATIONS

Hypersensitivity to any component of this product (4)

WARNINGS AND PRECAUTIONS

Systemic exposure to phenylephrine may cause elevations in blood pressure. (5.1)

ADVERSE REACTIONS

The most common reported adverse reactions ($\geq 2\%$) are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Rayner Surgical Inc. at 1-877-OMIDRIA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 04/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION

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4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

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16 HOW SUPPLIED/STORAGE AND HANDLING

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Omidria® is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

2 DOSAGE AND ADMINISTRATION

Omidria must be diluted prior to intraocular use. For administration to patients undergoing cataract surgery or intraocular lens replacement, 4 mL of Omidria is diluted in 500 mL of ocular irrigating solution. Irrigation solution is to be used as needed for the surgical procedure for a single patient.

The storage period for the diluted product is not more than 4 hours at room temperature or 24 hours under refrigerated conditions.

Do not use if the solution is cloudy or if it contains particulate matter.

3 DOSAGE FORMS AND STRENGTHS

Omidria is an intraocular solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL (0.3% w/v) of ketorolac for use in a single patient.

4 CONTRAINDICATIONS

Omidria is contraindicated in patients with a known hypersensitivity to any of its ingredients.

5 WARNINGS AND PRECAUTIONS

5.1 Elevated Blood Pressure

Systemic exposure to phenylephrine can cause elevations in blood pressure.

5.2 Cross-Sensitivity or Hypersensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory drugs (NSAIDs). There have been reports of bronchospasm or exacerbation of asthma associated with the use of ketorolac in patients who either have a known hypersensitivity to aspirin/NSAIDs or a past medical history of asthma. Therefore, use Omidria with caution in individuals who have previously exhibited sensitivities to these drugs.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Table 1 shows frequently reported ocular adverse reactions with an incidence of $\geq 2\%$ of adult patients as seen in the combined clinical trial results from three randomized, placebo-controlled studies [see Clinical Studies (14)].

Table 1: Ocular Adverse Reactions Reported by $\geq 2\%$ of Adult Patients

| MedDRA Preferred Term | Placebo (N=462) | Omidria (N=459) |
|---------------------------------|--------------------|--------------------|
| | n (%) | n (%) |
| Ocular Events | | |
| Anterior Chamber Inflammation | 102 (22%) | 111 (24%) |
| Intraocular Pressure Increased | 15 (3%) | 20 (4%) |
| Posterior Capsule Opacification | 16 (4%) | 18 (4%) |
| Eye Irritation | 6 (1%) | 9 (2%) |
| Foreign Body Sensation in Eyes | 11 (2%) | 8 (2%) |

In a safety study that enrolled 72 pediatric patients up to 3 years old, no overall difference in safety was observed between pediatric and adult patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Omidria use in pregnant women or animals to inform any drug-associated risks. Oral administration of ketorolac to rats during late gestation produced dystocia and increased pup mortality at a dose 740-times the plasma exposure at the recommended human ophthalmic dose (RHOD). Since human systemic exposure to Omidria following a lens replacement procedure is low [see Clinical Pharmacology (12.3)], the applicability of animal findings to the risk of Omidria in humans during pregnancy is unclear. Omidria should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Premature closure of the ductus arteriosus in the fetus has occurred with third trimester use of oral and injectable NSAIDs. Ketorolac plasma concentrations are detectable following ocular Omidria administration [see Clinical Pharmacology (12.3)]. The use of Omidria during late pregnancy should be avoided.

Data

Animal Data

No well-controlled animal reproduction studies have been conducted with Omidria or phenylephrine.

Ketorolac, administered during organogenesis, did not cause embryofetal abnormalities or mortalities in rabbits or rats at oral doses of 3.6 mg/kg/day and 10 mg/kg/day, respectively. These doses produced systemic exposure that is 1150 times and 4960 times the plasma exposure (based on C_{max}) at the RHOD, respectively. When administered to rats during late gestation (after Day 17 of gestation) at oral doses up to 1.5 mg/kg/day (740 times the plasma exposure at the RHOD), ketorolac produced dystocia and increased pup mortality.

8.2 Lactation

Risk Summary

There are no data on the presence of Omidria in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to Omidria, following a lens replacement procedure is low [see Clinical Pharmacology (12.3)]. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omidria and any potential adverse effects on the breastfed child from Omidria.

8.4 Pediatric Use

The safety and effectiveness of Omidria have been established in the pediatric population from neonates to adolescents (birth to younger than 17 years). Use of Omidria in this population is supported by evidence from adequate and well-controlled studies of Omidria in adults with additional data from a single active-controlled safety study in pediatric patients up to 3 years old [see *Clinical Studies (14)*].

No overall differences in safety were observed between pediatric and adult patients.

8.5 Geriatric Use

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

10 OVERDOSAGE

Systemic overdosage of phenylephrine may cause a rise in blood pressure. It may also cause headache, anxiety, nausea, vomiting, and ventricular arrhythmias. Supportive care is recommended.

11 DESCRIPTION

Omidria is a sterile aqueous solution, containing the α_1 -adrenergic receptor agonist phenylephrine HCl and the nonsteroidal anti-inflammatory ketorolac tromethamine, for addition to ocular irrigating solution.

The descriptions and structural formulae are:

Phenylephrine Hydrochloride Drug Substance:

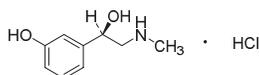
Common Name: phenylephrine hydrochloride

Chemical Name: (-)-*m*-Hydroxy- α -[(methylamino)methyl]benzyl alcohol hydrochloride

Molecular Formula: $C_{10}H_{13}NO_2 \cdot HCl$

Molecular Weight: 203.67 g/mole

Figure 1: Chemical Structure for Phenylephrine HCl



Ketorolac Tromethamine Drug Substance:

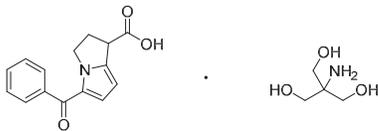
Common Name: ketorolac tromethamine

Chemical Name: (\pm)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid: 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

Molecular Formula: $C_{15}H_{13}NO_3 \cdot C_3H_7NO_3$

Molecular Weight: 376.40 g/mole

Figure 2: Chemical Structure for Ketorolac Tromethamine



Omidria is a clear, colorless to slightly yellow, sterile solution concentrate with a pH of approximately 6.3.

Each vial of Omidria contains:

Actives: phenylephrine hydrochloride 12.4 mg/mL equivalent to 10.16 mg/mL of phenylephrine and ketorolac tromethamine 4.24 mg/mL equivalent to 2.88 mg/mL of ketorolac.

Inactives: citric acid monohydrate; sodium citrate dihydrate; water for injection; may include sodium hydroxide and/or hydrochloric acid for pH adjustment.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The two active pharmaceutical ingredients (API) in Omidria, phenylephrine and ketorolac, act to maintain pupil size by preventing intraoperative miosis, and reducing postoperative pain.

Phenylephrine is an α_1 -adrenergic receptor agonist and, in the eye, acts as a mydriatic agent by contracting the radial muscle of the iris. Ketorolac is a nonsteroidal anti-inflammatory that inhibits both cyclooxygenase enzymes (COX-1 and COX-2), resulting in a decrease in tissue concentrations of prostaglandins to reduce pain due to surgical trauma. Ketorolac, by inhibiting prostaglandin synthesis secondary to ocular surgical insult or direct mechanical stimulation of the iris, also prevents surgically induced miosis.

12.3 Pharmacokinetics

In a pharmacokinetic study evaluating Omidria, systemic exposure to both phenylephrine and ketorolac was low or undetectable.

A single-dose of Omidria as part of the irrigation solution was administered in 14 patients during lens replacement surgery. The volume of irrigation solution used during surgery ranged between 150 mL to 300 mL (median 212.5 mL). Detectable phenylephrine plasma concentrations were observed in one of 14 patients (range 1.2 to 1.4 ng/mL) during the first 2 hours after the initiation of Omidria administration. The observed phenylephrine plasma concentrations could not be distinguished from the preoperative administration of phenylephrine 2.5% ophthalmic solution prior to exposure to Omidria.

Ketorolac plasma concentrations were detected in 10 of 14 patients (range 1.0 to 4.2 ng/mL) during the first 8 hours after the initiation of Omidria administration. The maximum ketorolac concentration was 15 ng/mL at 24 hours after the initiation of Omidria administration, which may have been due to application of postoperative ketorolac ophthalmic solution.

14 CLINICAL STUDIES

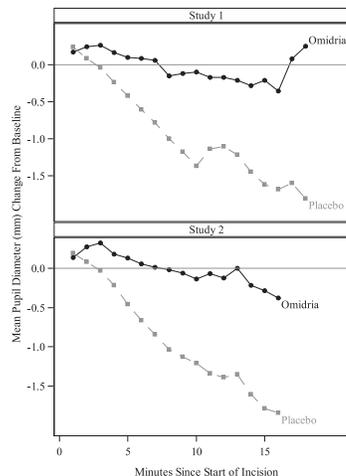
Studies in Adults

The efficacy and safety of Omidria were evaluated in two Phase 3, randomized, multicenter, double-masked, placebo-controlled clinical trials in 808 adult patients undergoing cataract surgery or intraocular lens replacement.

Patients were randomized to either Omidria or placebo. Patients were treated with preoperative topical mydriatic and anesthetic agents. Pupil diameter was measured throughout the surgical procedure. Postoperative pain was evaluated by self-administered 0-100 mm visual analog scales (VAS).

Mydriasis was maintained in the Omidria-treated groups while the placebo-treated groups experienced progressive constriction.

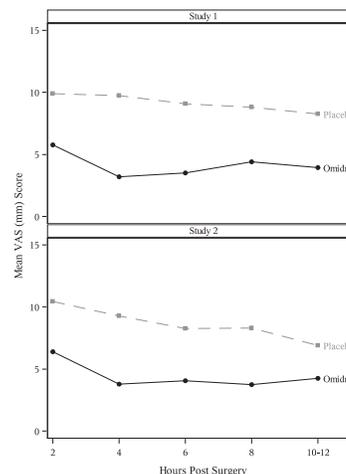
Figure 3: Intraoperative Pupil Diameter (mm) Change-from-Baseline



At the end of cortical clean-up, 23% of placebo-treated patients and 4% of Omidria-treated patients had a pupil diameter less than 6 mm ($p < 0.01$).

Pain during the initial 10-12 hours postoperatively was statistically significantly less in the Omidria-treated groups than in the placebo-treated groups.

Figure 4: Postoperative Mean Visual Analog Scale (VAS) Scores for Pain



During the 10-12 hours postoperatively, 26% of Omidria-treated patients reported no pain (VAS = 0 at all timepoints) while 17% of placebo-treated patients reported no pain ($p < 0.01$).

Study in Pediatric Patients

The safety of Omidria was evaluated in a single, randomized, multicenter, double-masked, active-controlled clinical study in 72 pediatric patients up to 3 years old undergoing cataract surgery with or without intraocular lens replacement.

Patients were randomized to either Omidria or phenylephrine. Patients were treated with preoperative topical mydriatic and anesthetic agents. As in the adult studies, mydriasis was maintained in the Omidria-treated group. No overall differences in safety were observed between pediatric and adult patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

Omidria (phenylephrine and ketorolac intraocular solution) 1%/0.3% is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution, for addition to ocular irrigating solution.

Omidria is supplied in a multi-pack containing:

4 vials: NDC 82604-600-04 or

10 vials: NDC 82604-600-10

Storage: Store at 20° to 25°C (68° to 77°F). Protect from light.

17 PATIENT COUNSELING INFORMATION

Inform patients that they may experience sensitivity to light.

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Bellevue, WA 98007

Patented product see
www.rayner.com/patents
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640069
Revised: 04/2023
US-OM-2300042 04/23



OMIDRIA®

(phenylephrine and ketorolac
intraocular solution)
1% / 0.3%