OMIDRIA®

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

Billing and Reimbursement Guide

- Codes and guidance on completing claim forms for Medicare Fee-for-Service, Medicare Advantage, and commercial payers
- Billing and reimbursement information for OMIDRIA
- Details on ordering OMIDRIA
- Helpful resources

Rayner

About OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%

OMIDRIA is the first and only FDA-approved drug that provides continuous intracameral delivery of an NSAID and a mydriatic agent during cataract surgery.[1]

OMIDRIA is a non-opioid medication added to the irrigating solution used during cataract surgery and lens replacement[1]

Provides direct and continuous intracameral delivery of an NSAID and a mydriatic agent, delivered at the site of care.[1]

Optimize time. Maximize control. Go dropless with OMIDRIA.

- **Streamlines** cataract surgery
- **Effectively maintains pupil dilation** and requires less use of PEDs[1-8]
- **Reduces complications** such as IFIS, CME, and breakthrough iritis[7]
- **Improved patient experience** with less pain, greater visual acuity, and fewer to no drops[1,2,9,10]
- **Places control** and **surgical outcomes** in surgeon's hands
- **Minimizes the risks and liabilities** of compounded products

CME=Cystoid Macular Edema; **IFIS**=Intraoperative Floppy Iris Syndrome; **NSAID**=Nonsteroidal Anti-inflammatory Drug; **PED**=Pupil Expansion Device.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

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

Coding for OMIDRIA*

OMIDRIA has a unique permanent J-code†

J1097[11]

phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL

1 billing unit = 1 mL; one standard 4-mL vial = 4 units.

Sample CPT® codes[13]	CPT modifier[12]
66984 Uncomplicated cataract surgery **66982**‡ Complex cataract surgery **66983, 66989, 66991, 66988** Related intraocular lens procedures	**RT/LT** Right eye/Left eye

HCPCS and NDC codes for OMIDRIA

HCPCS code[11]	APC	HCPCS modifier[14, 15]	Long descriptor[11]	NDC number[1, 20]
J1097	9324	JZ** TB***	Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL	82604-0600-04 (11-digit)

Important reminders

- The OMIDRIAssure program provides assistance for financially eligible uninsured or underinsured patients and those with insufficient commercial insurance†
- Questions related to a patient's eligibility for OMIDRIAssure should be addressed by calling the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), contacting your OMIDRIA Field Reimbursement Manager, or working directly with your payer provider representative
- Coverage and payment may vary by payer, contractual agreements, and site of service

INDICATIONS AND USAGE

OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic 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.

IMPORTANT SAFETY INFORMATION

The most commonly reported adverse reactions at ≥ 2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

CPT is a registered trademark of the American Medical Association.

*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of OMIDRIA in eligible patients. Rayner does not guarantee reimbursement. OMIDRIAssure program services are subject to change without notice.

‡If surgery is for complex cataract surgery, physician should note the ICD-10-CM code or reason why the surgery is complex.

CPT=Current Procedural Terminology; **HCPCS**=Healthcare Common Procedure Coding System; **ICD-10-CM**=International Classification of Diseases, Tenth Revision, Clinical Modification; **NDC**=National Drug Code, **APC**=Ambulatory Payment Classification.

** Used in ASC and HOPD

*** Used in 340b Hospitals

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

OMIDRIA®
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Sample CMS-1500 Paper Claim Form[16]

Enter all applicable patient information

Item 21:
Enter "0" if using ICD-10-CM

Item 21:
Enter the Diagnosis Code(s)

Item 24A:
Enter N4 qualifier and 11-digit NDC number and UN1

Item 24B:
"24" indicates an ASC
"22" indicates HOPD

Item 24D:
Enter applicable procedure code (eg, 66984 for uncomplicated cataract surgery)

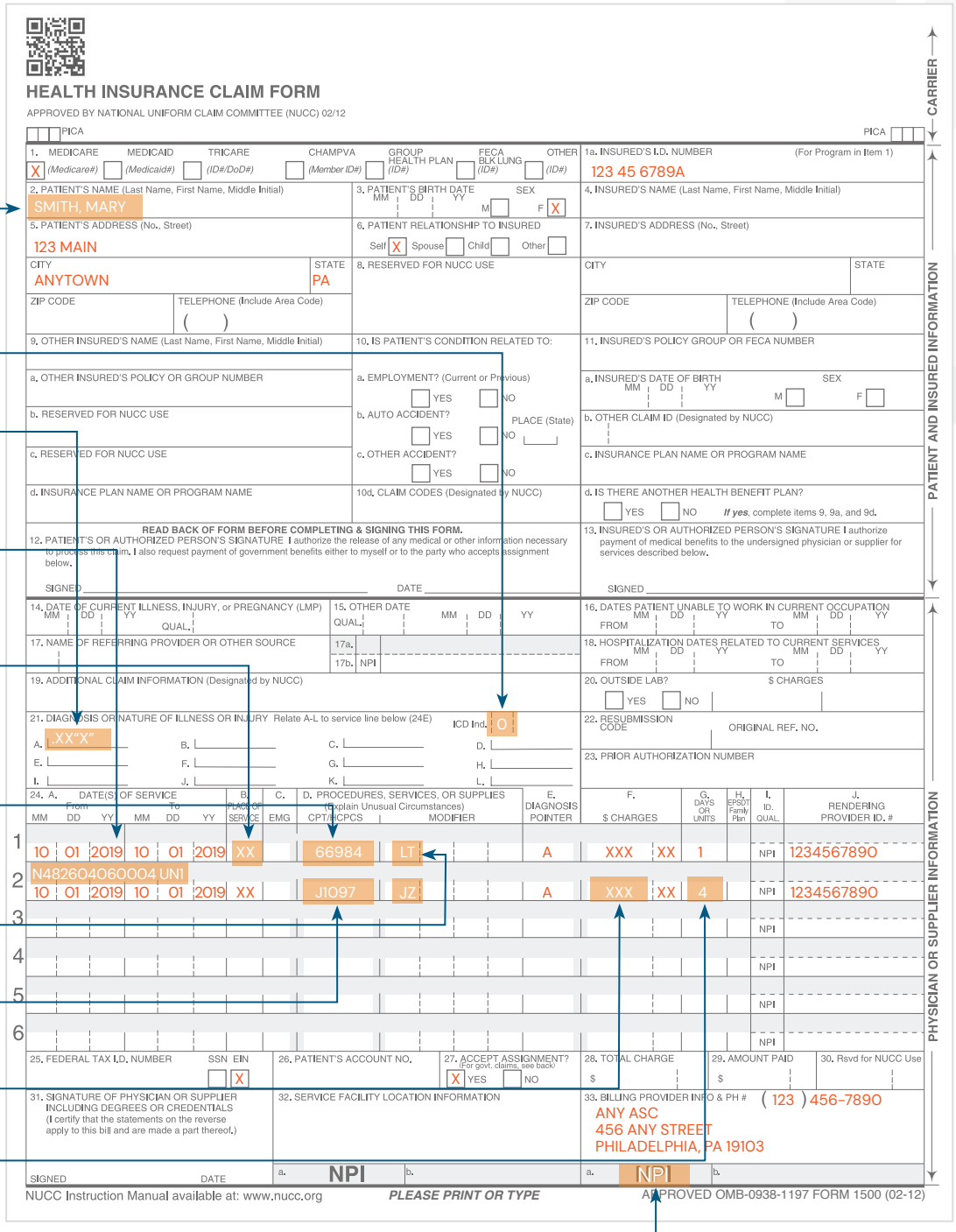
Item 24D:
Enter Modifier for left eye (LT) or right eye (RT) with the JZ modifier

Item 24D:
Enter unique Billing Code for OMIDRIA

Item 24F:
Enter charges for OMIDRIA

Item 24G:
Enter 4 units

Item 33a:
Entry of NPI number is required



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

CARRIER

PATIENT AND INSURED INFORMATION

1. MEDICARE X — 1a. INSURED'S I.D. NUMBER: 123 45 6789A
2. PATIENT'S NAME: SMITH, MARY
3. PATIENT'S BIRTH DATE SEX: M X
5. PATIENT'S ADDRESS: 123 MAIN
6. PATIENT RELATIONSHIP TO INSURED: Self X
CITY: ANYTOWN STATE: PA
ZIP CODE / TELEPHONE (Include Area Code)

PHYSICIAN OR SUPPLIER INFORMATION

24. A. DATE(S) OF SERVICE From	To	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 — 10 01 2019	10 01 2019	XX		66984	LT	A	XXX	1		NPI	1234567890
2 — N482604060004 UN1 10 01 2019	10 01 2019	XX		J1097	JZ	A	XXX	4		NPI	1234567890
3										NPI	
4										NPI	
5										NPI	
6										NPI	

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: A. XX"X" — ICD Ind. 0
25. FEDERAL TAX I.D. NUMBER — SSN EIN X
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? X YES
28. TOTAL CHARGE $
29. AMOUNT PAID $
30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS
32. SERVICE FACILITY LOCATION INFORMATION
33. BILLING PROVIDER INFO & PH # (123) 456-7890
ANY ASC
456 ANY STREET
PHILADELPHIA, PA 19103
a. NPI
a. NPI

NUCC Instruction Manual available at: www.nucc.org — PLEASE PRINT OR TYPE — APPROVED OMB-0938-1197 FORM 1500 (02-12)

Information contained herein is provided as a reference for obtaining reimbursement. This content is for informational purposes only. Rayner does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. Contact 1-877-OMIDRIA (1-877-664-3742) for more information about how to submit for OMIDRIA reimbursement.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; **NDC**=National Drug Code; **NPI**=National Provider Identifier.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

OMIDRIA®
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1% / 0.3%

Sample UB-04 (CMS-1450) Paper Claim Form[17]

Form Locator 4:
Enter 4-digit code that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 013. The final digit is usually a "1," meaning one claim for the event

Enter all applicable patient information

Form Locator 17:
Enter Patient Status

Form Locator 47:
Enter charges for OMIDRIA

Form Locator 42*:
Enter Revenue Code

Form Locator 43:
Enter N4 qualifier and 11-digit NDC number and UN1

Form Locator 44:
Enter unique Billing Code for OMIDRIA and modifier (JZ) *Note 340b add TB modifier.

Form Locator 44:
Enter Procedure Code(s)

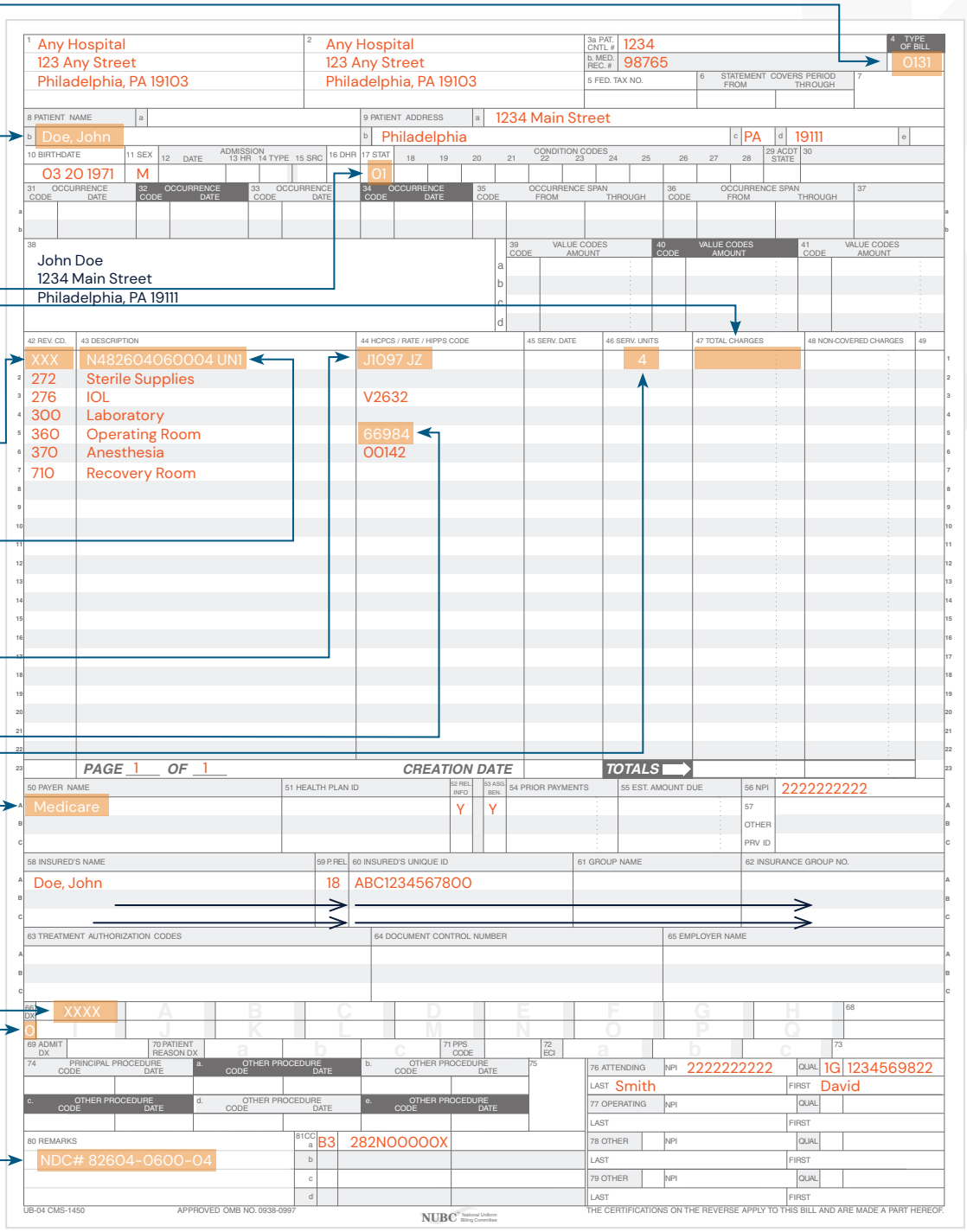
Form Locator 46:
Enter 4 units

Form Locator 50A:
If Medicare is the primary payer, enter "Medicare" on line A

Form Locator 67:
Enter primary Diagnosis Code

Form Locator 66:
Enter "0" if using ICD-10-CM

Form Locator 80:
Used to display remarks or additional information that may be needed to process a claim



*Note: For hospitals and ASCs using UB-04 form, it is a best practice to confirm the correct revenue code with the payer to ensure reimbursement.

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. Rayner does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. Contact 1-877-OMIDRIA (1-877-664-3742) for more information about how to submit for OMIDRIA reimbursement.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification;
IOL=Intraocular lens; **NDC**=National Drug Code.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

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Understanding Billable Status for Patients Receiving OMIDRIA

Patient insurance benefits are typically comprised of primary and additional coverage that determine billable status

Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*

	Medicare Fee-for-Service (FFS; Part B, or Legacy Medicare)	Medicare Advantage (Part C, or Replacement or Advantage)	Commercial	Other Government
Step 1: Primary Insurance				
Step 2: Additional Insurance	Medicare Supplemental (Medigap)		Medicare Part A/B†	Medicaid
	Medicaid			TRICARE/DOD
	Other			Veterans Health Administration

*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Patients with Medicare Part B will not be eligible for company programs.

DOD=Department of Defense; **FFS**=Fee-for-Service.

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Medicare Fee-for-Service Billing and Reimbursement

HCPCS and NDC codes for OMIDRIA

HCPCS code[11]	APC	HCPCS modifier[14, 15]	Long descriptor[11]	NDC number[1, 20]
J1097	9324	JZ* TB**	Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL	82604-0600-04 (11-digit)

Reimbursed with separate payment

OMIDRIA has separate payment status in ASCs and HOPDs for 100% of fee-for service Medicare patients***

For OMIDRIA reimbursement in the **ASC** setting, CMS reimburses **80%** of the current Medicare Fee schedule.

For OMIDRIA in the **HOPD** setting, CMS reimburses **100%** of the current Medicare fee schedule.

OMIDRIAssure®
SUPPORT AT EVERY STEP

The OMIDRIAssure program offers patients options to assist with the cost of OMIDRIA:

We Pay the Difference patient reimbursement program for commercially insured patients.†

Equal Access patient assistance program for financially eligible uninsured or underinsured patients.

Field Reimbursement Managers are highly experienced in helping you navigate through the reimbursement pathway.

For personalized help, call the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), 8 AM–8 PM ET, Monday–Friday‡

* Used in ASC and HOPD

** Used in 340b Hospitals

*** OMIDRIA qualifies for separate payment across both ASC and HOPD settings as it fulfills the requirements established in the non-opioid as a surgical supply provision by CMS.

† Based on your Medicare or commercial plan selection, there may be a patient responsibility for OMIDRIA.

‡ Benefit verifications may not address contracted payer payment rates.

APC=Ambulatory Payment Classifications; **ASC**=Ambulatory Surgery Center; **HCPCS**=Healthcare Common Procedure Coding System; **HOPD**=Hospital Outpatient Department; **NDC**=National Drug Code.

Many medications require coinsurance . Healthcare providers are contractually obligated to collect applicable patient responsibility. Failure to adhere to regulations may lead to legal issues under the False Claims Act and Anti-Kickback Statue or result in audits and reimbursement penalties from insurers, including exclusion from federal healthcare programs. CMS Fraud Waste and Abuse disallows regular waive of coinsurance.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

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Medicare Advantage Billing and Reimbursement

- In the Contract Year 2024 MA and Part D final rule published April 2023, CMS updated rules for Medicare Advantage (Part C) plans to make clear what they must cover and how they decide on what is necessary care. CMS regulations at §422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan's service area.[18]
- In 2024, 54% of Medicare beneficiaries were enrolled in MA plans, with projections indicating an increase to 64% by 2033.[19]

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, Medicare Advantage plans should cover OMIDRIA, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations*
- For a Medicare Advantage patient, the specific Medicare Advantage payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for dealing with Medicare Advantage plans

- Before surgery, verify if patient has a Medicare Advantage plan
- Check if your facility-specific payer contracts follow Medicare guidelines or allow for separate payment of drugs and biologics (carve outs)
- If the plan bundles payment for OMIDRIA, share the CMS announcement regarding separate billable status

You can look up a patient's Medicare plan by entering the patient's name and date of birth in any of the following databases, among others:

- Secure Provider Online Tool (SPOT), provided by First Coast MAC
- Availity (for BCBS, Aetna, Humana)
- Palmetto e-services
- Noridian Medicare Portal

You do not need to pay a subscription fee to access these databases

EQUAL ACCESS

PATIENT ASSISTANCE PROGRAM

Assistance for financially eligible uninsured or underinsured patients

For patients who meet certain financial criteria, Rayner has established the Equal Access Patient Assistance Program as part of OMIDRIAssure.†

- Eligible patients will receive OMIDRIA at no cost
- Free vial will be sent to your facility prior to surgery
- Application for free vial must be completed and approved at least 5 days prior to date of surgery

* Rayner does not guarantee payment by any payer.

† To be eligible for the Equal Access Patient Assistance Program, patients must be enrolled prior to surgery. Program is subject to change without notice. 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.

BCBS=Blue Cross Blue Shield; **CMS**=Centers for Medicare & Medicaid Services; **FFS**=Fee-for-Service; **MA**=Medicare Advantage.

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Commercial Insurance Billing and Reimbursement

May reimburse with bundled payment

- Of all insurance types, commercial payers are the most likely to bundle payment for OMIDRIA with that for the cataract surgery procedure

Payment rate will vary by plan

- The amount commercial payers will reimburse for use of OMIDRIA may be dependent on the terms in the contract with the payer
- Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*

Identify the Payer Methodology

- How is the payment rate structured across the various payers?*
- For a commercial patient, the specific payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for commercial payers

- Check if your facility-specific payer contracts allow for separate payment of drugs and biologics (carve outs)
- Verify payer-specific use of appropriate revenue code
- Cultivate relationship with payer-provider network representative

WE PAY THE DIFFERENCE

PATIENT REIMBURSEMENT PROGRAM

Assistance for patients with insufficient commercial insurance

- Rayner will cover the OMIDRIA cost difference between the facility's acquisition cost and the allowed amount of the commercially insured patient's insurance.†
- Visit https://www.omidria.com/access-and-support to download the We Pay the Difference Enrollment Form, We Pay the Difference Instruction Form, and other available resources

Reach out to our FRM team for additional support by emailing omidriafrms@rayner.com or by calling 1-844-RAYNER1 (1-844-729-6371)

* Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

† OMIDRIAssure program services are subject to change without notice. The We Pay the Difference Patient Reimbursement Program patient benefit is not available for patients with any government insurance. Rayner does not guarantee reimbursement. Facility acquisition cost is determined after application of any volume-based discount. Claims must be submitted within 90 days of date of surgery. Rayner does not guarantee coverage or reimbursement.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

OMIDRIA®
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Ordering OMIDRIA for Your Facility

How to order OMIDRIA

OMIDRIA is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution. The smallest sellable unit is a carton, which contains four (4) single-patient-use vials.

NDC#: 82604-600-04

*Use the 10-digit NDC for ordering and the 11-digit NDC for billing.

One (1) carton is the minimum order. OMIDRIA is sold only in carton quantities. OMIDRIA is not sold in individual vial quantities.

x1 x4

One (1) carton contains four (4) single-patient-use vials*

x30 x120

One (1) case contains thirty (30) cartons (120 total vials)

OMIDRIA is available through specialty distributors

McKesson Specialty Distribution†

Item number: 5016421
Contact number: 1-800-482-6700

McKesson Plasma and Biologics†

Item number: 2856201
Contact number: 1-877-625-2566

Cardinal Health Specialty Distribution‡

Item number: 5875778
Contact number: 1-855-855-0708

Besse Medical

Item number: 10283186
Contact number: 1-888-767-7123

AmerisourceBergen Specialty Distribution§

Item number: 10283069
Contact number: 1-800-746-6273

FFF Enterprises, Inc.

(Offering consignment services)

Item number: OMI4060004
Contact number: 1-800-843-7477

McKesson Medical-Surgical

Item number: 1278880
Contact number: 1-855-571-2100

† For customers of McKesson full-line wholesaler division, OMIDRIA is available for purchase through McKesson Plasma and Biologics and McKesson Specialty Distribution.

‡ For customers of Cardinal full-line wholesaler division, OMIDRIA is available for purchase through Cardinal Health Specialty Distribution.

§ For customers of AmerisourceBergen Corporation full-line wholesale division, OMIDRIA is available through AmerisourceBergen specialty distribution and can be ordered using the Passport ordering platform through AmerisourceBergen.

NDC=National Drug Code.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com

OMIDRIA®
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1% / 0.3%

HELPFUL RESOURCES*

www.cms.gov

- ASC (Addendum BB) and HOPD (Addendum A) Payment Rates and Updates
- CMS Quarterly Update
- MLN Matters Articles

https://www.omidria.com/access-and-support

- We Pay the Difference Instruction Form
- We Pay the Difference Enrollment Form
- OMIDRIAssure Patient Certification Form
- Billing and Reimbursement Guide

*Rayner does not guarantee the accuracy, completeness, or current status of information provided on third-party websites.

ASC=Ambulatory Surgery Center; ASP=average sales price; CMS=Centers for Medicare & Medicaid Services; HOPD=hospital outpatient department; MLN=Medicare Learning Network®.

INDICATIONS AND USAGE

OMIDRIA® is added to ophthalmic 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.

IMPORTANT SAFETY INFORMATION

OMIDRIA must be added to irrigating solution prior to intraocular use.

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

Systemic exposure of phenylephrine may cause elevations in blood pressure.

Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory drugs (NSAIDs), or have a past medical history of asthma.

The most commonly reported adverse reactions at ≥2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Please see the Full Prescribing Information for OMIDRIA.

You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References: 1. OMIDRIA [package insert]. Bellevue, WA: Rayner Surgical Inc. 2023. **2.** 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. **3.** Al-Hashimi S, Donaldson K, Davidson R, et al. Medical and surgical management of the small pupil during cataract surgery. *J Cataract Refract Surg.* 2018;44:1032-1041. **4.** Bucci FA Jr, Michalek B, Fluet 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. **5.** Matossian C. Clinical and economic outcomes in cataract surgery using phenylephrine 1.0%-Ketorolac 0.3% in a real-world setting. Abstract presented at: Annual Meeting of the American Society of Cataract and Refractive Surgeons (ASCRS); April 16, 2018; Washington, DC. Course 5219. **6.** 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. **7.** 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. **8.** Silverstein SM, R ana 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. **9.** 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. **10.** Donnenfeld ED, Hovanesian JA, Malik AG, Wong A. A randomized, prospective, observer-masked study comparing dropless treatment regimen using intracanalicular dexamethasone insert, intracameral ketorolac, and intracameral moxifloxacin versus conventional topical therapy to control postoperative pain and inflammation in cataract surgery. *Clin Ophthalmol.* 2023;17:2349-2356. **11.** 2025 Healthcare Common Procedure Coding System. Accessed December 29, 2025. https://hcpcs.codes/j-codes/J1097/ **12.** Billing and Coding: Cataract Extraction (including Complex Cataract Surgery) A58592, Medicare Coverage Database CMS.gov; Billing and Coding: Use of Laterality Modifiers A56860, Medicare Coverage Database CMS.gov **13.** Jagmin CL, Levy BS, Ashley SM eds, et al.CPT 2025 Professional Edition. American Medical Association.2024. **14.** New JZ Clains Modifier for Certain Medicare Part B Drugs. MM 13056. CR 13056. CMS Medicare Learning Network June 2, 2023 **15.** Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. MLN Fact Sheet MLN4800856. CMS Medicare Learning Network, November 2024. **16.** Professional Paper Claim Form (CMS-1500). CMS.gov. September 10, 2024. **17.** CMS-1450 Medicare Uniform Institutional Provider Bill. CMS.gov.June 6, 2023. **18.** Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Federal Register April 12, 2023. https://www.federalregister.gov/d/2023-07115/p-728 accessed June 9, 2025. **19.** Medicare Advantage in 2024: enrollment Update and Key Trends. Meredith Freed, JF Biniek, A. Domico and T Neuman. KFF Aug 8th, 2024. **20.** U.S. Food & Drug National Drug Code Directory. Accessed January 5, 2026 https://www.accessdata.fda.gov/scripts/cder/ndc/

Rayner

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

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 (≥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*

*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 ≥ 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 ≥ 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.

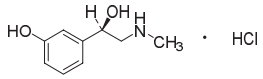
10 OVERDOSAGE
Systemic overdosage of phenylephrine may cause a rise in blood pressure. It may also cause headache, anxiety, nausea, vomiting, and ventricular arrhythmias. Supportive care is recommended.

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:

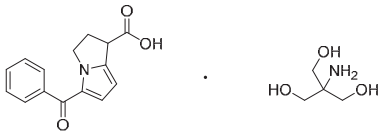
Phenylephrine Hydrochloride Drug Substance:
Common Name: phenylephrine hydrochloride
Chemical Name: **(-)-m-Hydroxy-α-**[(methylamino)methyl]benzyl alcohol hydrochloride
Molecular Formula: $C_9H_{13}NO_2 \cdot HCl$
Molecular Weight: 203.67 g/mole

Figure 1: Chemical Structure for Phenylephrine HCl



Ketorolac Tromethamine Drug Substance:
Common Name: ketorolac tromethamine
Chemical Name: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid: 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)
Molecular Formula: $C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$
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.

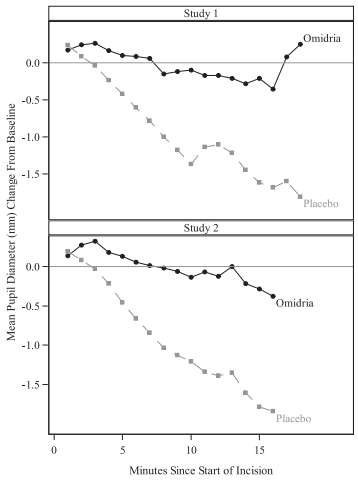
Ketorolac plasma concentrations were detected in 10 of 14 patients (range 1.0 to 4.2 ng/mL) during the first 8 hours after the initiation of Omidria administration. The maximum ketorolac concentration was 15 ng/mL at 24 hours after the initiation of Omidria administration, which may have been due to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

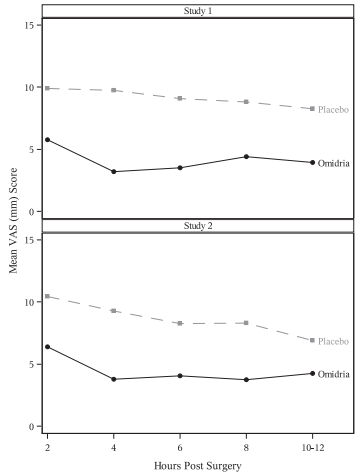
Figure 3: Intraoperative Pupil Diameter (mm) Change-from-Baseline



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.

Rayner Surgical Inc.
Suite 102, 14335 NE 24th Street
Bellevue, WA 98007

Patented product see www.rayner.com/patents for further details.

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