CardinalHealth™

# URGENT: DRUG RECALL
# Ophthalmic Drug Products

March 23, 2026

Dear Customer:

This letter is to inform you of a product recall involving:

| Product Name | Package Description | Brand Name | NDC | Lot Number | Expiration Date |
|---|---|---|---|---|---|
| Tetrahydrozoline Ophthalmic Solution, 0.05% | 0.5 fl.oz. (15 mL) | Rugby® | 0536-1217-94 | RG24E01 | 05/2026 |
| Lubricating Eye Drops (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%) | 0.5 fl.oz. (15 mL) | Rugby® | 0536-1219-94 | SY24K01 | 09/2026 |
| | | | | SY24K02 | 09/2026 |
| Artificial Tears (Polyvinyl Alcohol, 0.5% and Povidone, 0.6%), | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0011-1 | AT24D01 | 04/2026 |
| | | | | AT24E01 | 05/2026 |
| | | | | AT24G01 | 07/2026 |
| Dry Eye Relief (Glycerin, 0.2%, Hypromellose, 0.2%, and Polyethylene Glycol 400, 1%) | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0502-1 | LT24F01 | 06/2026 |
| | | | | LT24G01 | 07/2026 |
| Ultra Lubricating Eye Drops (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%) | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0457-1 | SU24E01 | 05/2026 |
| | | | | SU24E02 | 05/2026 |
| | | | | SU24K01 | 09/2026 |
| Original Eye Drops (Tetrahydrozoline HCl, 0.05%) | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0454-1 | RG24E01 | 05/2026 |
| Redness Relief (Glycerin, 0.25%, Naphazoline HCl, 0.012%) | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0010-1 | RL24F01 | 06/2026 |
| | | | | RL24F02 | 06/2026 |

Please see enclosed product labeling.

This voluntary recall has been initiated by K.C. Pharmaceuticals due to potential concerns regarding the validation of the Company's aseptic filling process for the period between March 27, 2024 and November 07, 2024. Use of this product may result in eye infection.

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We began shipping this product on April 10, 2024.

Immediately examine your inventory and quarantine products subject to recall. In addition, if you may have further distributed these products, please identify your wholesale and retail customers and notify them at once of this product recall. Please direct your customers to return the product subject to recall to the place of purchase. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall should be carried out to the retail level. Your assistance is appreciated and necessary to prevent patient harm.

Please complete and fax the enclosed response form as soon as possible even if you do not have the recalled products and fax to 1-877-574-5031 or email to cardinalhealth4156@sedgwick.com. A prepaid UPS Return Service label will be provided so the affected product can be shipped to:

Sedgwick, Inc.
Attention: Event # 4156
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you have any questions regarding this notification, please contact Sedgwick, Inc. at 1-877-650-7694 (8:00 am – 5:00 pm Monday through Friday).

This recall is being made with the knowledge of the Food and Drug Administration.

*Electronically signed by:*
*Aimee Albanese*
*Reason: Author*
*Date: Mar 23, 2026*
*08:16:22 EDT*

Aimee Albanese
Manager, QRA

Enclosure(s)

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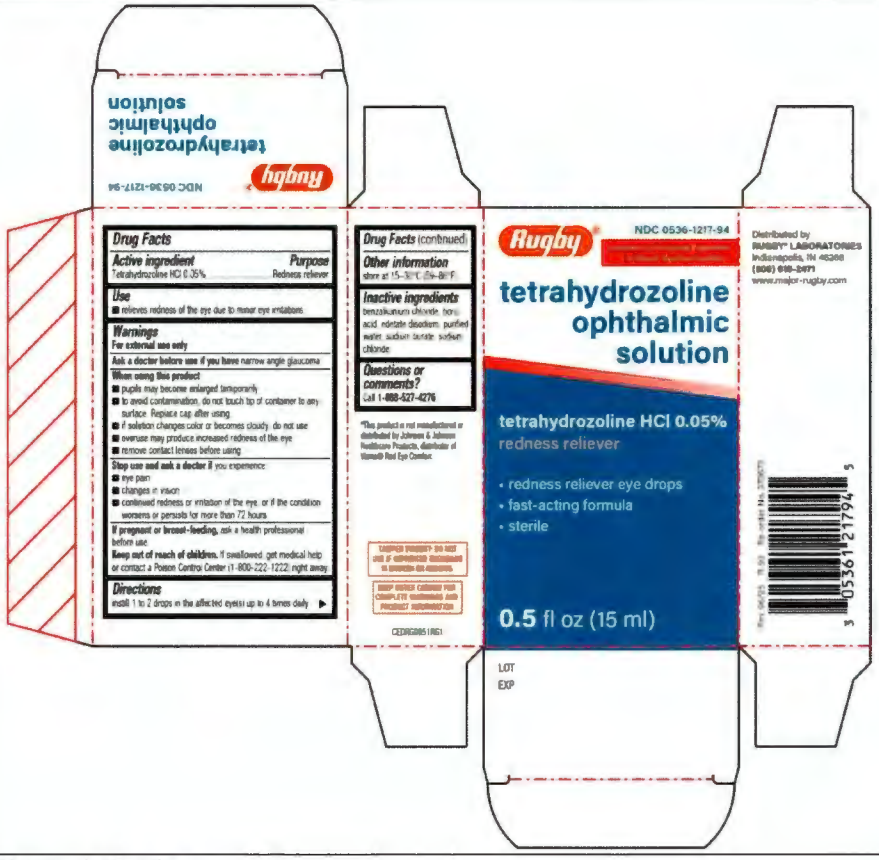
Enclosure (s)

Example Labeling for Tetrahydrozoline Ophthalmic Solution, 0.05% [0.5 fl.oz. (15 mL)], NDC 0536-1217-94

Carton Labeling




Bottle Labeling

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Example Labeling for Lubricating Eye Drops (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%), 0.5 fl.oz. (15 mL), NDC 0536-1219-94

Carton Labeling


Bottle Labeling


Enclosure (s)

CardinalHealth™

Example Labeling for Artificial Tears (Polyvinyl Alcohol, 0.5% and Povidone, 0.6%), 0.5 fl.oz. (15 mL), NDC 70000-0011-1

Carton Labeling


Bottle Labeling

Example Labeling for Dry Eye Relief (Glycerin, 0.2%, Hypromellose, 0.2%, and Polyethylene Glycol 400, 1%), 0.5 fl.oz. (15 mL), NDC 70000-0502-1

Carton Labeling


Bottle Labeling

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Example Labeling for Ultra Lubricating Eye Drops (Polyethylene Glycol 400, 0.3% and Propylene Glycol, 0.3%), 0.5 fl.oz. (15 mL), NDC 70000-0457-1

## Carton Labeling


## Bottle Labeling

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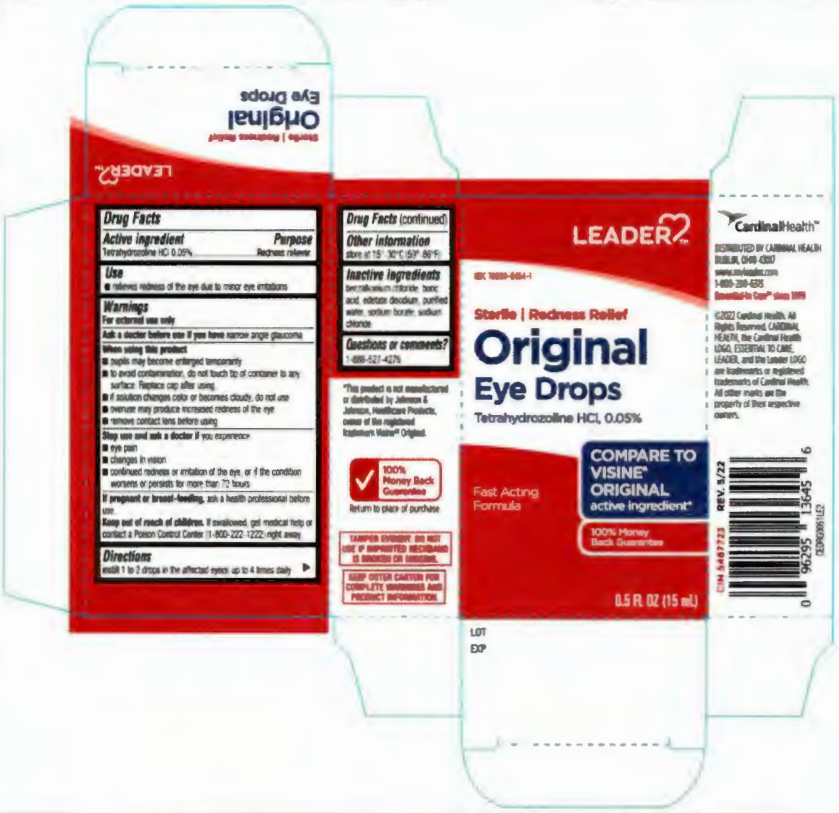
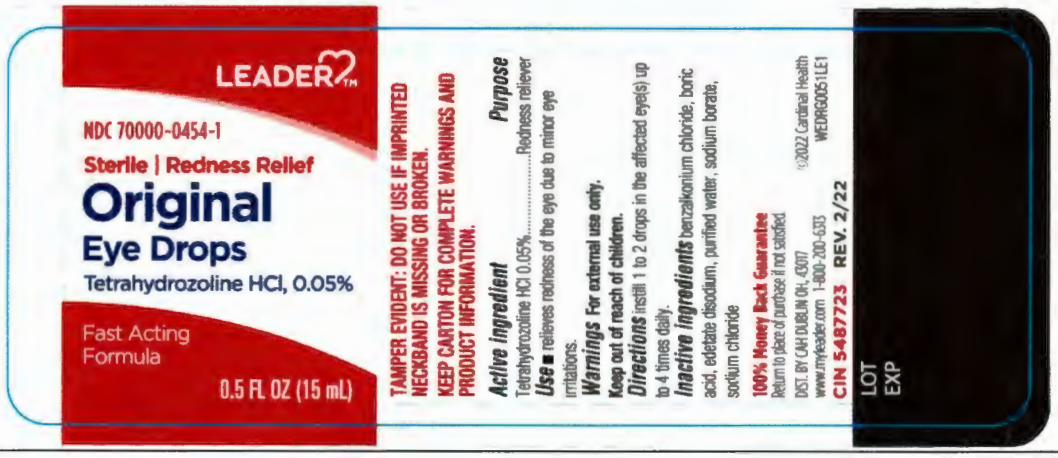
Example Labeling for Original Eye Drops (Tetrahydrozoline HCl, 0.05%), 0.5 fl.oz. (15 mL), NDC 70000-0454-1

Carton Labeling




Bottle Labeling



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Example Labeling for Redness Relief (Glycerin, 0.25%, Naphazoline HCl, 0.012%), 0.5 fl.oz. (15 mL), NDC 70000-0010-1

Carton Labeling


Bottle Labeling




4156_01_09AS_V1.1

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# URGENT: DRUG RECALL – RESPONSE FORM / PACKING SLIP

**Please make a copy of this form to include with your product return shipment.**

Your timely response to the recall notification is requested. Please complete form and fax to 1-877-574-5031 or email to cardinalhealth4156@sedgwick.com.

| Product Name | Package Description | Brand Name | NDC | Lot Numbers | # of Bottles |
|---|---|---|---|---|---|
| Tetrahydrozoline Ophthalmic Solution | 0.5 fl.oz. (15 mL) | Rugby® | 0536-1217-94 | RG24E01 | |
| Lubricating Eye Drops | 0.5 fl.oz. (15 mL) | Rugby® | 0536-1219-94 | SY24K01, and SY24K02 | |
| Artificial Tears | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0011-1 | AT24D01, AT24E01, and AT24G01 | |
| Dry Eye Relief | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0502-1 | LT24F01 and LT24G01 | |
| Ultra Lubricating Eye Drops | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0457-1 | SU24E01, SU24E02, and SU24K01 | |
| Original Eye Drops | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0454-1 | RG24E01 | |
| Redness Relief | 0.5 fl.oz. (15 mL) | LEADER™ | 70000-0010-1 | RL24F01 and RL24F02 | |

**Please check ALL appropriate boxes.**

- ☐ I have read and understand the recall instructions provided in the March 23, 2026 letter.
- ☐ We have quarantined and will return recalled product on hand.
- ☐ We do not have any of the recalled product on hand.
- ☐ I have identified and notified my wholesale and retail customers that were shipped or may have been shipped this product by:

  Date _____ Method of Notification: _____

**Any adverse events associated with recalled product?** ☐ Yes or ☐ No

If yes, please explain: _____

**Please check the appropriate box to describe your business:**

| | | |
|---|---|---|
| ☐ Wholesaler/Distributor | ☐ Hospital Pharmacies | ☐ Pharmacy – Retail |
| ☐ Hospital/Medical Facility | ☐ Repacker | ☐ Other:_____ |

**Complete the following information:**

| | | | |
|---|---|---|---|
| Name: | | | |
| Place of Business Name: | | | |
| Street Address, City, State, Zip: | | | |
| Phone or Email: | | | |
| Wholesaler Name: | | Wholesaler Account #: | |
| Debit Memo #: | | | |
| Signature/Date: | | | |

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