



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.



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.

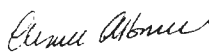
This recall should be carried out to the retail level. Your assistance is appreciated and necessary to prevent patient harm.

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)

Enclosure (s)

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

Carton Labeling



Drug Facts
Active ingredient
 Tetrahydrozoline HCl 0.05%
Purpose
 Redness reliever

Use
 Relieves redness of the eye due to minor eye irritations.

Warnings
 For external use only
 Ask a doctor before use if you have narrow angle glaucoma.
 When using this product:
 • pupils may become enlarged temporarily.
 • to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
 • if solution changes color or becomes cloudy, do not use.
 • overuse may produce increased redness of the eye.
 • remove contact lenses before using.
 Stop use and ask a doctor if you experience:
 • eye pain
 • changes in vision
 • continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
 Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

Drug Facts (continued)
Other information
 Store at 15°-30°C (59°-86°F).

Inactive ingredients
 benzalkonium chloride, boric acid, sodium disodium purified water, sodium borate, sodium chloride.

Questions or comments?
 Call 1-800-527-4276.

Questions or comments?
 *This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Rugby Red Eye Center.

CAUTION: Tamper Evident Seal (TES) is missing or broken. Do not use.

KEEP OUT OF REACH OF CHILDREN. KEEP THIS PRODUCT COMPLETELY CLOSED AND PROPERLY SECURED.

LOT
EXP

rugby NDC 0536-1217-94

tetrahydrozoline ophthalmic solution

tetrahydrozoline HCl 0.05% redness reliever

- redness reliever eye drops
- fast-acting formula
- sterile

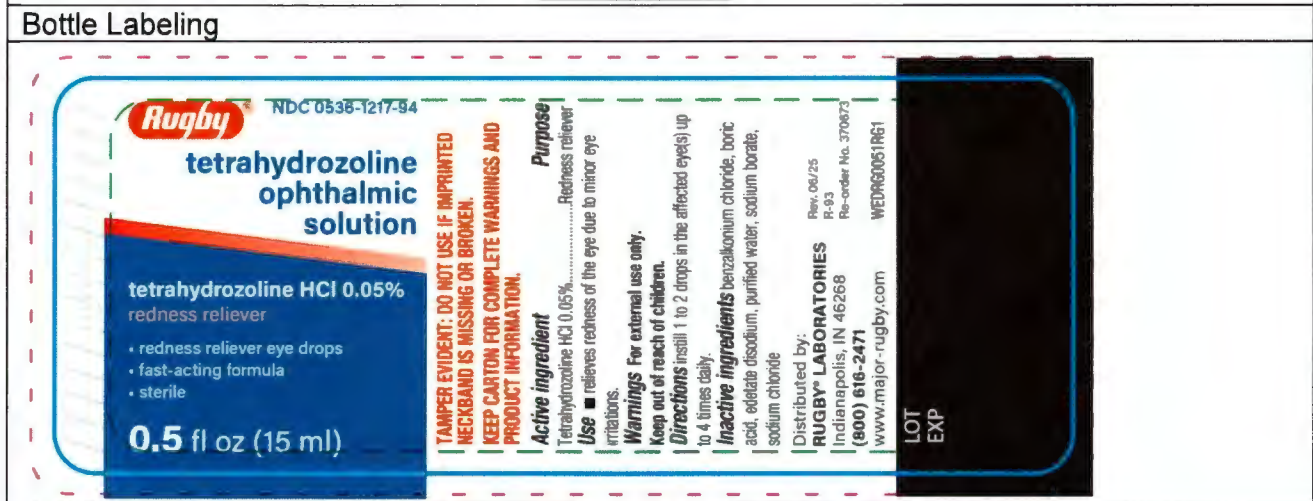
0.5 fl oz (15 ml)

Distributed by: **RUGBY® LABORATORIES**, Indianapolis, IN 46268
 (800) 616-2471
 www.major-rugby.com

Rev. 06/25
 R-93
 File-order No. 370673
 WEDR00051R61

3 0536 121794 5

Bottle Labeling



rugby NDC 0536-1217-94

tetrahydrozoline ophthalmic solution

tetrahydrozoline HCl 0.05% redness reliever

- redness reliever eye drops
- fast-acting formula
- sterile

0.5 fl oz (15 ml)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Purpose
 Tetrahydrozoline HCl 0.05%.....Redness reliever

Use
 Relieves redness of the eye due to minor eye irritations.

Warnings
 For external use only. Keep out of reach of children.

Directions
 Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

Inactive ingredients
 benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, sodium chloride

Distributed by:
RUGBY® LABORATORIES
 Indianapolis, IN 46268
 (800) 616-2471
 www.major-rugby.com

Rev. 06/25
 R-93
 File-order No. 370673
 WEDR00051R61

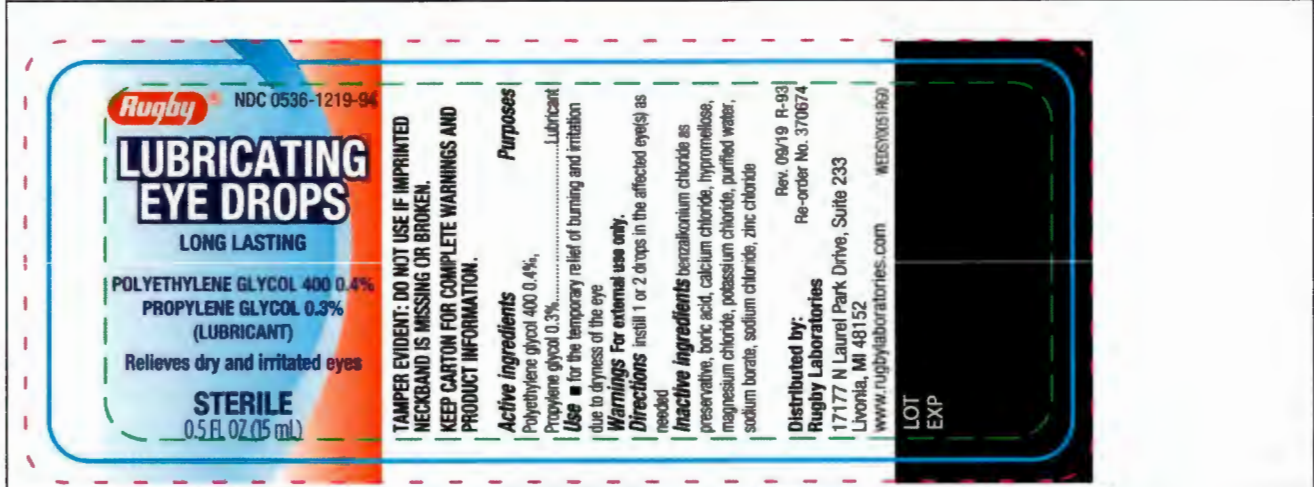
LOT
EXP

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)



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

Artificial Tears
Sterile | Lubricant Eye Drops

LEADER

Drug Facts

Active Ingredients	Purposes
Polyvinyl alcohol 0.5% Povidone 0.6%	Lubricant Lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun

Warnings

For external use only

- Do not use this product if
 - scratches, changes color, or becomes cloudy
- When using this product
 - remove contact lens before using
 - to avoid contamination, do not touch tip of container to any surface
 - replace cap after using, keep container tightly closed

Stop use and see a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours

Keep out of the reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center. 800.222.1222 (immediately)

Drug Facts (continued)

Directions

- instill 1 or 2 drops in the affected eye(s) as needed
- children under 6 years of age ask a doctor

Other information

- store at 15°-30°C (59°-86°F)

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?
Call 1-888-827-4276

*This product is not manufactured or distributed by Medibach Products Inc., owner of the registered trademark Murine® Tears.

Artificial Tears
Sterile | Lubricant Eye Drops

NDC 70000-0011-1

Artificial Tears
Polyvinyl Alcohol, 0.5% | Povidone, 0.6%
Lubricant

COMPARE TO MURINE® TEARS
active ingredients*

100% Money Back Guarantee

Relieves Dry and Irritated Eyes

100% Money Back Guarantee

0.5 FL. OZ. (15 mL)

LOT
EXP

CardinalHealth™
DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.zephyros.com
1-800-200-5315
Essential to Care™ since 1890

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100% Money Back Guarantee
Return to place of purchase if not satisfied

REV. 4/19

0 96205 13764 4

CARTON/CSLEO

Bottle Labeling

LEADER

NDC 70000-0011-1

Artificial Tears
Sterile | Lubricant Eye Drops

Polyvinyl Alcohol, 0.5%
Povidone, 0.6% | Lubricant

Relieves Dry and Irritated Eyes

0.5 FL. OZ. (15 mL)

Purposes

Polyvinyl alcohol 0.5%
Povidone 0.6%
Lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

For external use only.

Directions

instill 1 to 2 drops in the affected eye(s) as needed.

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic and sodium phosphate monobasic

Questions or comments? 1-888-827-4276
Dist. by CAH, Dublin, OH 43017
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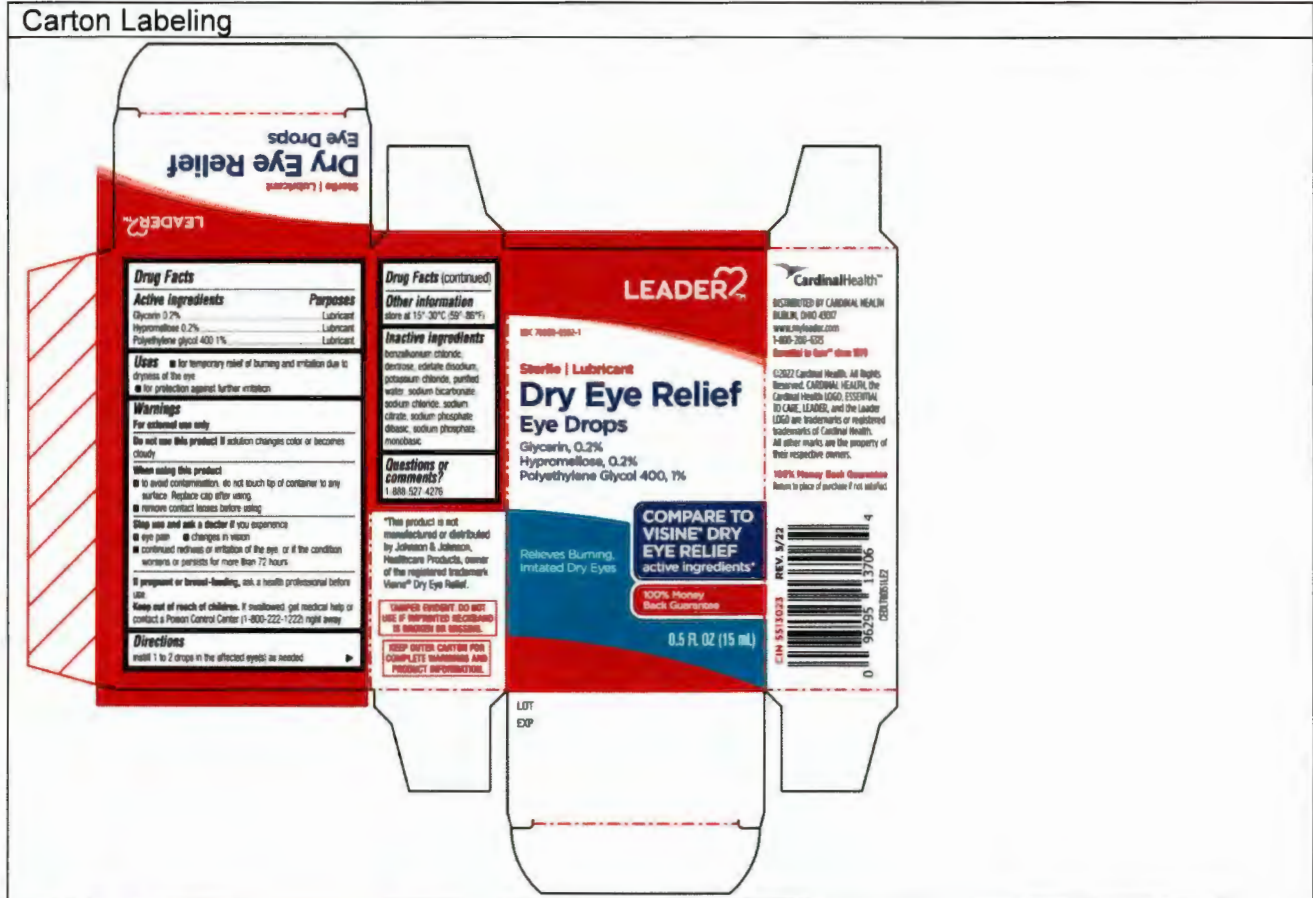
CIN 5515234 REV. 09/19 WARTER052LEO

LOT
EXP

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
HECKBOARD IS MISSING OR BROKEN.
KEEP CARTON FOR COMPLETE WARNINGS AND
PRODUCT INFORMATION.

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



Drug Facts

Active Ingredients	Purposes
Glycerin 0.2%	Lubricant
Hypromellose 0.2%	Lubricant
Polyethylene glycol 400 1%	Lubricant

Uses ■ for temporary relief of burning and irritation due to dryness of the eye
■ for protection against further irritation

Warnings
For external use only
Do not use this product if solution changes color or becomes cloudy

When using this product
■ To avoid contamination, do not touch tip of container to any surface. Replace cap after every use.
■ Remove contact lenses before using.
Stop use and ask a doctor if you experience:
■ eye pain ■ changes in vision
■ continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours.
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
Instill 1 to 2 drops in the affected eye(s) as needed.

Drug Facts (continued)

Other information
Store at 15°-30°C (59°-86°F)

Inactive ingredients
benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic.

Questions or comments?
1-888-527-4276

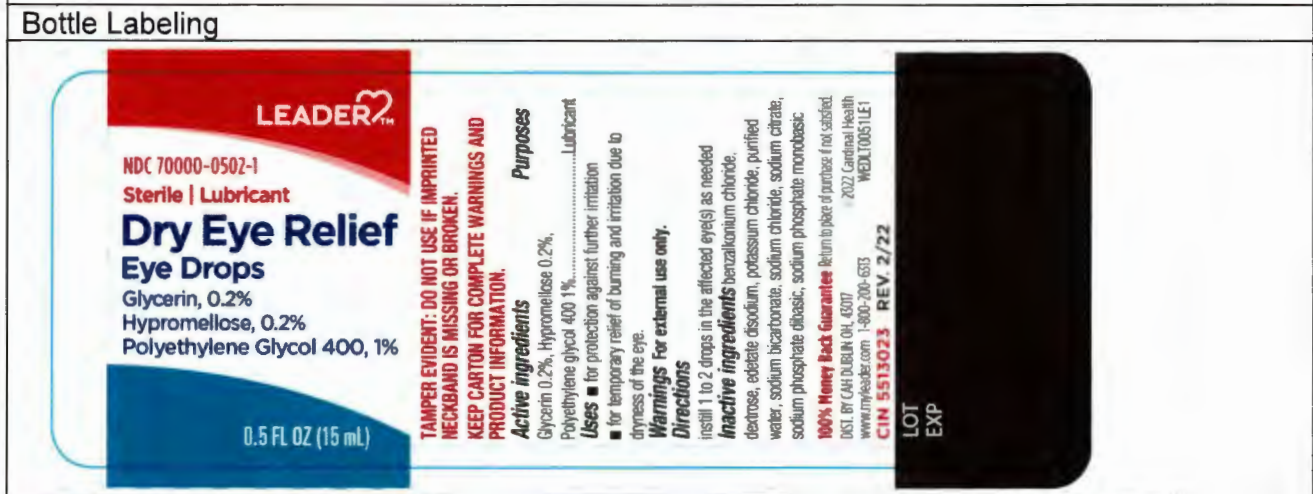
"This product is not manufactured or distributed by Johnson & Johnson, Healthcare Products, owner of the registered trademark Visine® Dry Eye Relief."

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

LOT
EXP

Bottle Labeling



NDC 70000-0502-1
Sterile | Lubricant
Dry Eye Relief Eye Drops
Glycerin, 0.2%
Hypromellose, 0.2%
Polyethylene Glycol 400, 1%

0.5 FL OZ (15 mL)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Active ingredients
Glycerin 0.2%, Hypromellose 0.2%, Polyethylene glycol 400 1%.....Lubricant

Purposes
■ for protection against further irritation
■ for temporary relief of burning and irritation due to dryness of the eye.

Warnings For external use only.

Directions
instill 1 to 2 drops in the affected eye(s) as needed

Inactive ingredients benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic.

100% Money Back Guarantee: Return to place of purchase if not satisfied.

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www.myleader.com 1-800-200-6333
WEXL100511E1

CIN 5513023 REV. 2/22

LOT
EXP



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

LEADER²
Sterile | High Performance

Ultra Lubricating Eye Drops

Polyethylene Glycol 400, 0.4%
Propylene Glycol, 0.3%
Lubricant

Relieves Dry and Irritated Eyes

0.5 fl oz (15 mL)

100% Money Back Guarantee
Return to place of purchase if not satisfied.

COMPARE TO SYSTANE[®] ULTRA LUBRICANT EYE DROPS active ingredients*

100% Money Back Guarantee

LOT
EXP

Drug Facts
Active ingredients
Polyethylene glycol 400, 0.4%
Propylene glycol, 0.3%
Purpose
Lubricant
Lubricant

Uses
For the temporary relief of burning and irritation due to dryness of the eye.

Warnings
For external use only
Do not use
If this product changes color or becomes cloudy
If you are sensitive to any ingredient in this product
When using this product
Do not touch the tip of container to any surface to avoid contamination
Replace cap after each use
Stop use and ask a doctor if
You feel eye pain
Changes in vision occur
Redness or irritation of the eyes gets worse or lasts more than 72 hours
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
Instill 1 or 2 drops in the affected eye(s) as needed.
Children under 6 years of age, ask a doctor.

Other information
RETURN THIS CARTON FOR FULL REFUND
Age of use temperature

Active ingredients
Aminomethylpropanol, benzalkonium chloride as preservative, boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sorbitol

Questions or comments?
1-800-222-4276

*This product is not manufactured or distributed by Alcon Laboratories, Inc., owner of the registered trademark Systane[®] Ultra Lubricant Eye Drops

100% Money Back Guarantee
Return to place of purchase if not satisfied.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Purposes
Lubricant

Active ingredients
Polyethylene glycol 400, 0.4%
Propylene glycol, 0.3%

Use
For the temporary relief of burning and irritation due to dryness of the eye

Warnings
For external use only.

Directions
Instill 1 or 2 drops in the affected eye(s) as needed

Inactive ingredients
aminomethylpropanol, benzalkonium chloride as preservative, boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sorbitol

100% Money Back Guarantee
Return to place of purchase if not satisfied.
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WEDS00051LE0

CIN 5487756 REV. 09/19

LOT
EXP

0 96295 13648 117
0280021E1

Bottle Labeling

LEADER²
Sterile | High Performance

Ultra Lubricating Eye Drops

Polyethylene Glycol 400, 0.4%
Propylene Glycol, 0.3%
Lubricant

Relieves Dry and Irritated Eyes

0.5 fl oz (15 mL)

100% Money Back Guarantee
Return to place of purchase if not satisfied.

COMPARE TO SYSTANE[®] ULTRA LUBRICANT EYE DROPS active ingredients*

100% Money Back Guarantee

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Purposes
Lubricant

Active ingredients
Polyethylene glycol 400, 0.4%
Propylene glycol, 0.3%

Use
For the temporary relief of burning and irritation due to dryness of the eye

Warnings
For external use only.

Directions
Instill 1 or 2 drops in the affected eye(s) as needed

Inactive ingredients
aminomethylpropanol, benzalkonium chloride as preservative, boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sorbitol

100% Money Back Guarantee
Return to place of purchase if not satisfied.
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WEDS00051LE0

CIN 5487756 REV. 09/19

LOT
EXP



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

Carton Labeling

Bottle Labeling

LEADER²

NDC 70000-0454-1

Sterile | Redness Relief

Original
Eye Drops

Tetrahydrozoline HCl, 0.05%

Fast Acting Formula

0.5 FL OZ (15 mL)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS MISSING OR BROKEN. KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Purpose
Tetrahydrozoline HCl 0.05%.....Redness reliever

Active ingredient
Tetrahydrozoline HCl 0.05%.....Redness reliever

Use ■ relieves redness of the eye due to minor eye irritations.

Warnings For external use only. Keep out of reach of children.

Directions Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

Inactive ingredients benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, sodium chloride

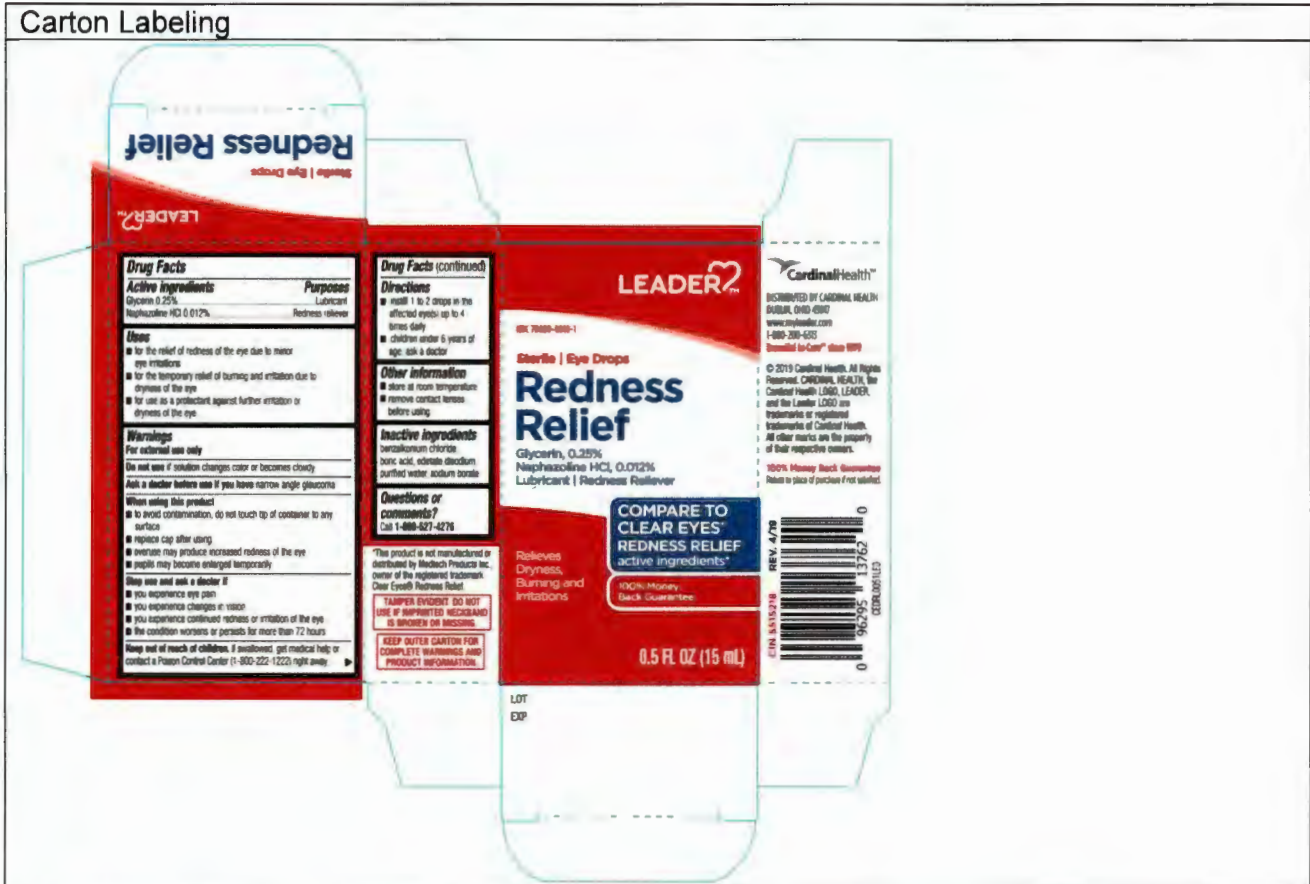
100% Money Back Guarantee
Return to place of purchase if not satisfied.

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CIN 5487723 REV. 2/22

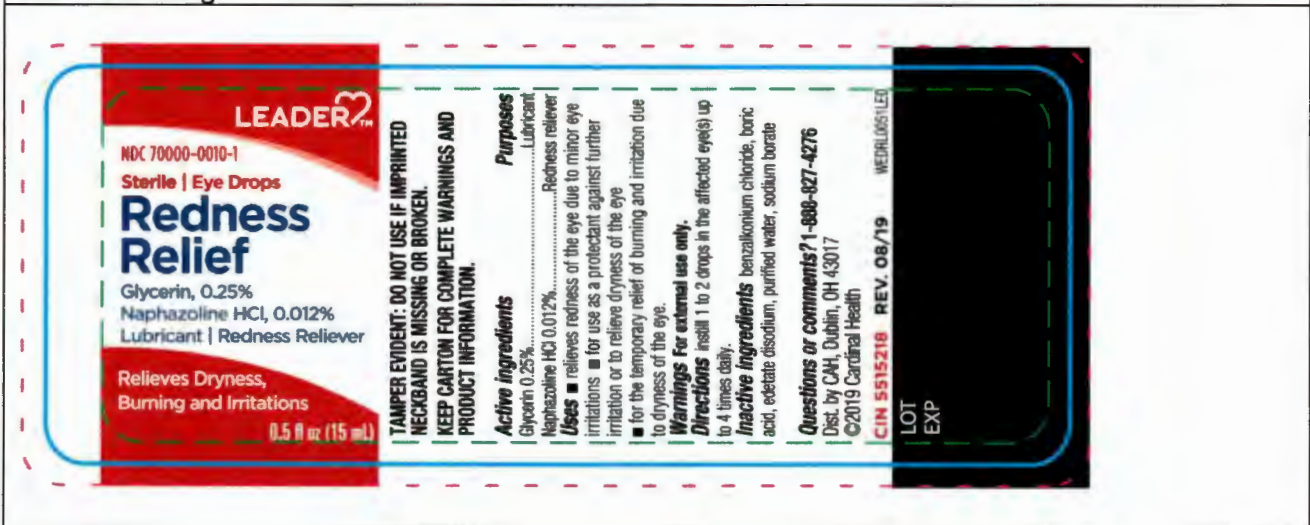
LOT
EXP

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





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:

- | | | |
|--|--|--|
| <input type="checkbox"/> Wholesaler/Distributor | <input type="checkbox"/> Hospital Pharmacies | <input type="checkbox"/> Pharmacy – Retail |
| <input type="checkbox"/> Hospital/Medical Facility | <input type="checkbox"/> Repacker | <input type="checkbox"/> 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:		

4156_01_10AS_V1.1



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