6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

URGENT: DRUG RECALL	
Description	Systane® Night Gel and GenTeal® Tears Severe lubricant eye gels
Product Reference	Systane® Night Gel *NDC: 0065-0474-01* GenTeal® Tears Severe Gel *NDC: 0065-8064-01*
Market Action Identifier	2026.002

April 21, 2026

CESAR CASTILLO INC
ROAD #1 KM 21.1
GUAYNABO, PR 971
Account# 100042146

Respond electronically

https://qrco.de/Systane-GenTeal-response
As an alternative, respond via email/fax using Response Form on subsequent pages

Dear CESAR CASTILLO INC,

Alcon is initiating a recall of Systane® Night Gel and GenTeal® Tears Severe lubricant eye gels at the recommendation of the U.S. Food and Drug Administration. The recall applies to all unexpired products produced by a third-party contract manufacturer in Europe, due to FDA inspection observations that it believes may impact product quality. No other Alcon products are affected.

This recall is being carried out to the retail level. Alcon is requesting that you dispose of all batches of the impacted product within your inventory, and post the attached *Product Recall Notice* for retail end-customer notification. See product details below, and **Table 1** for product lots distributed to your facility.

Systane® Night Gel NDC: 0065-0474-01	**GenTeal® Tears Severe gel** NDC: 0065-8064-01
	

Alcon

6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

Actions to be taken by the Customer:

Our records indicate that you have received Systane® Night Gel, and GenTeal® Tears Severe lubricant eye gels. **We request that you identify and discard any remaining units from your inventory.** This recall should be communicated to the consumer.

Please take the following steps:

- ☐ Immediately examine your inventory to determine if you have any inventory of *Systane® Night Gel* and *GenTeal® Tears Severe* lubricant eye gels. **No other Alcon products are affected by this event**.
- ☐ Quarantine and discard any remaining units of *Systane® Night Gel* and *GenTeal® Tears Severe* lubricant eye gels.
- ☐ On the attached Response Form, please indicate the quantity discarded even if you have zero (0) units remaining in inventory.
- ☐ If you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or by posting the attached Recall Notice in retail locations.
- ☐ Respond to Alcon indicating your understanding of the included instructions by **completing our online response form at** https://qrco.de/Systane-GenTeal-response or by completing the attached *"Response Form"* and returning to Alcon via email or fax.

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

Should you have any questions or concerns about this matter or need further assistance, please contact Alcon Customer Service or your Alcon Sales Representative.

Sincerely,

Heather Attra
SVP, Chief Quality and Regulatory Affairs Officer

Alcon

6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

Table 1: Impacted Product Distributed to your Facility

Product Description	Lot/Batch #	Expiry Date	Date Distributed
Systane® Night Gel GenTeal® Tears Severe Gel	2U47 8V54 9T21 9T50 9V39 9V97	05/31/2026 01/31/2027 04/30/2026 04/30/2026 02/28/2027 02/28/2027	8/5/2024 - 11/6/2025

6201 South Freeway
Fort Worth, Texas 76134-2099
www.alcon.com

RESPONSE FORM

MA 2026.002 Systane® Night Gel and GenTeal® Tears Severe Gel	CESAR CASTILLO INC ROAD #1 KM 21.1 GUAYNABO, PR 971 Account# 100042146

Respond electronically

https://qrco.de/Systane-GenTeal-response

As an alternative, respond via email/fax per the steps below

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions, including identification and notification of my firm's affected customer letter.

☐ I have checked my stock. I have identified and discarded all impacted products. Report total number of packs discarded below.

Units of product discarded: _____

☐ I have notified my customers per my firm's recall procedures.

Respond to Alcon indicating your understanding of the included instructions by **completing the online response form at** https://qrco.de/Systane-GenTeal-response or by completing and returning this "*Response Form*" and returning to Alcon via email or fax.

Fax: 817-302-4337 **Email**: Market.Actions@alcon.com

Your signature below confirms your understanding of the recall instructions and your commitment to identify and notify your firm's affected customers.

Signature of Representative:	**Date:**
Name and Title:	
Packs Discarded:	

NOTICE OF PRODUCT RECALL

Customers should immediately discontinue use of any remaining units of **Systane® Night Gel** and **GenTeal® Tears Severe** lubricant eye gels. Please contact the retailer for instructions on how to obtain a refund. No other Alcon products are affected.

Systane® Night Gel
NDC: 0065-0474-01

GenTeal® Tears Severe gel
NDC: 0065-8064-01

In the event you have experienced adverse events or product quality issues related to this communication, please report these occurrences to Alcon via web (https://notifeye.alcon.com), by email (msus.safety@alcon.com) or by phone (1-800-757-9780) Monday through Friday, 8:00 AM to 5:00 PM, Central Time.

Adverse events or quality issues experienced with the use of these products may also be reported to the FDA MedWatch Adverse Event Reporting program: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm.

Retailer: Please post until May 31, 2026