



Alcon Laboratories (Malaysia) Sdn. Bhd.
Level 20-1, Tower B, Plaza 33, No. 1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor, Malaysia.
Phone: +6(03)-27826888
Fax: +6(03)-27836950

URGENT: VOLUNTARY MEDICAL DEVICE RECALL	
Description	Voluntary Recall of specific lots of GenTeal® Lubricant Eye Gel & GenTeal® Lubricant Eye Drops
Product Reference	GenTeal® Lubricant Eye Gel GenTeal® Lubricant Eye Drops
Market Action Identifier	2026.002

27-Apr-26



DKSH Malaysia Sdn Bhd
3, Jalan Sepintas 26/13,
HICOM Industrial Estate Seksyen 26,
40400 Shah Alam, Selangor
Account# 100615348

Dear DKSH Malaysia Sdn. Bhd,

Alcon is initiating a voluntary recall of GenTeal® Lubricant Eye Gel & GenTeal® Lubricant Eye Drops 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.

This recall is being carried out to the retail level. Alcon is requesting that you dispose/return all batches of the impacted products remaining within your inventory to the warehouse, 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.

Table 1:

Product Name	GenTeal® Lubricant Eye Gel	GenTeal® Lubricant Eye Drops
Product Illustration	 <p>Lubricant Eye Gel 10 g</p> <p>STERILE A MD</p> <p>Alcon</p>	 <p>Lubricant Eye Drops</p> <p>STERILE A</p> <p>10 mL Alcon</p>
Affected Lot No. & Expiry	Lot 5T81, 30 Jun 2026	Lot 8T34, Exp 31 May 2026
		Lot 3V09, Exp 30 Jun 2026

Actions to be taken by the Customer:

Our records indicate that you have received GenTeal® Lubricant Eye Gel & GenTeal® Lubricant Eye Drops. **We request that you identify and dispose/return any remaining units from your inventory to the warehouse.** 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 *GenTeal® Lubricant Eye Gel & GenTeal® Lubricant Eye Drops*.
- Quarantine and discard/return any remaining units of *GenTeal® Lubricant Eye Gel & GenTeal® Lubricant Eye Drops* to the warehouse.
- On the attached Response Form, please indicate the quantity disposed/returned even if you have zero (0) units remaining in inventory.



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- 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 the attached "*Response Form*" and returning to Alcon via email.

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,

A handwritten signature in blue ink that reads "Adlyt A." with a small flourish at the end.

Adulyarit Adulyapichet
GEM SEA QA Manager



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Table 1: Impacted Product Distributed to your Facility

Product Description	Lot/Batch #	Expiry Date
GENTEAL GEL 0.3% 10G-MAL	5T81	30 Jun 2026
GENTEAL DROPS 0.3% 10ML-MAL	3V09	30 Jun 2026
GENTEAL DROPS 0.3% 10ML-MAL	8T34	31 May 2026



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RESPONSE FORM

MA 2026.002
GenTeal® Lubricant Eye Gel and GenTeal®
Lubricant Eye Drops

DKSH Malaysia Sdn Bhd
3, Jalan Sepintas 26/13,
HICOM Industrial Estate Seksyen 26,
40400 Shah Alam, Selangor
Account# 100615348

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 disposed/returned all impacted products. Report total number of packs discarded below.

Units of product disposed/returned: _____

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

Respond to Alcon indicating your understanding of the included instructions by completing and returning this "Response Form" and returning to Alcon via email or fax.

Email: azzeem.nazri@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 **GenTeal® Lubricant Eye Gel and GenTeal® Lubricant Eye Drops**. Please contact the retailer for instructions on how to obtain a refund. No other Alcon products are affected.



Retailer: Please post until 30 Jun 2026