



# URGENT DRUG RECALL

## LUMIGAN® 0.01%, 7.5 mL

March 20, 2017

Dear Customer:

This is to advise you of Allergan's voluntary recall of *one lot* of LUMIGAN® 0.01%, 7.5 mL, Lot 92577. Our records indicate that you have received one or more shipments of this lot. Refer to sections *PRODUCT INFORMATION* and *RECALL INFORMATION* for additional information about the recall.

The reason for recall, health hazard assessment, and instructions for returning the affected product lot are given in the sections below. We ask that you follow our instructions in (1) notifying your customers (direct accounts down to the retail level) that received the affected product lot, (2) responding to the recall notification, and (3) returning the recalled merchandise.

Allergan has informed the U.S. Food and Drug Administration of this voluntary recall.

### PRODUCT INFORMATION

Lot	Product	NDC	Size	Dates Distributed	Exp. Date
92577	LUMIGAN 0.01%	0023-3205-08	7.5 mL	10/7/2016 - 01/31/2017	JUN-2018

### RECALL INFORMATION

Level:	<b><i>This recall is being conducted to the Retail/Health Care Provider (HCP) Level.</i></b>
Reason:	Product sample testing results did not meet the regulatory specification for individual and total impurities.
Health Hazard Assessment:	The Health Hazard Assessment of safety data did not suggest an increased patient safety risk with the use of this product at this time.

### ACTIONS REQUIRED

Upon receipt of this letter, please take the following actions:

1. If you have inventory of the recalled product lot 92577, take precautions to prevent use by quarantining the recalled product inventory. In addition, cease supplying the recalled product lot 92577 to your customers.
2. Carry out a physical count of the affected product in your possession and record the count on the enclosed postage paid Business Reply Card (BRC) and Packing slip.
3. Mail the postage paid BRC within five (5) business days of receipt. To assure that we can account for all recalled product, **it is imperative that you return the BRC.**
4. When returning the recalled product, attach the prepaid *FedEx* Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to:  
**GENCO Pharmaceutical Services (GPS), a subsidiary of FedEx Supply Chain**  
**6101 North 64<sup>th</sup> Street, Milwaukee, WI 53218**
5. If you have further distributed any of the affected product lot, we ask that you notify these customers down to the retail level. In your notification to your customers, please include our ACTIONS REQUIRED and CONTACT INFORMATION for returning the recalled merchandise.
6. Please note that if you are an HCP receiving this letter, you would have received this product through Allergan's Patient Assistance Program: RxHOPE. Patients need not be notified of this recall.
7. Please Do Not return any product lots that are not the subject of this recall.

Please contact GENCO Pharmaceutical Services if you have any questions about these recall actions.

### CONTACT INFORMATION

<b>Product Returns</b> Contact GPS, a subsidiary of FedEx Supply Chain at: 855-633-1417, 7 am - 5 pm CST	<b>Adverse Events/Product Complaints</b> Contact Allergan at: 1-800-433-8871, 8am - 8pm EST
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**FDA contact information for reporting adverse events/quality complaints:**  
Online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or call FDA at 1-800-FDA-1088

We appreciate your cooperation in this product recall, and regret any inconvenience that this may have caused.

***At Allergan our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.***

Thank you for your assistance in this matter.

Sincerely,  
Allergan