

RETAIL LEVEL RECALL

10/24/17

Dear Member,

This is to advise you of Allergan's voluntary recall, to the **retail level**, of Seven lots of **COMBIGAN 0.2/0.5** and One lot **of LUMIGAN 0.01**

Allergan chose to initiate this recall due to product sample testing results did not meeting the regulatory specifications for individual and total impurities.

The probability of an adverse event occurring, related to exposure to the identified impurities, is considered unlikely.

PRODUCTS RECALLED BY ALLERGAN

MUTUAL ITEM #	<u>PRODUCT</u>	SIZE	NDC Number	<u>LOT #'S</u>
645-184	COMBIGAN OPHTH SOL 0.2/0.5%	5 ml	0023-9211-05	94715,94757, 94715A,95297
217-190	COMBIGAN OPHTH SOL 0.2/0.5%	15 ml	0023-9211-15	95220
N/A	COMBIGAN OPHTH SOL 0.2/0.5%	2.5 ml	0023-9211-03	94659
645-192	COMBIGAN OPHTH SOL 0.2/0.5%	10 ml	0023-9211-10	95223
821-470	LUMIGAN OPHTH SOL 0.01%	2.5 ml	0023-3205-03	92575

With this recall, you are asked to:

- Check your product for the affected Lot.
- Stop dispensing and quarantine all impacted product.
- DO NOT RETURN PRODUCT TO MUTUAL DRUG.
- Complete attached Business Reply Form and return to GENCO per instructions.
- Contact Brent Slaughter if you have additional questions.



Allergan Drug Recall Program October 23, 2017



000673 North Carolina Mutual Whsle Drug-ED 816 Ellis Road Durham, NC 27703

Business Reply Form / Packing Slip

Your timely response to this recall notification is requested. Please fill out all applicable fields and return this form within (5) business days regardless if you have product or not.

Combigan 0.2% / 0.5%

NDC / Strength	Recalled Lots	Expiration Date	Bottles Being Returned
0023-9211-05	94715	01/2019	
	94757	02/2019	
	94715A	01/2019	
	95297	03/2019	
0023-9211-03	94659	02/2019	
0023-9211-10	95223	03/2019	
0023-9211-15	95220	03/2019	

Lumigan 0.01%

NDC / Strength	Recalled	Expiration	Bottles Being
	Lots	Date	Returned
0023-3205-03	92575	06/2018	

Please select one from each Section A and
Section B:
SectionA:
☐ We <u>have</u> stock of the above recalled product and will return the stock.
☐ We do not have any stock of the above recalled product and will not be making a return. Section B:
☐ We <u>have</u> notified all of our Consignees to return the recalled product.
☐ We do not have any Consignees for these lots.

Name:	Phone #:	Date:	
Signature:	Debit Memo #:		
Wholesaler:	DEA#		

***Please make a copy of this completed form to include with your product return <u>AND</u> either mail the original to GENCO using the prepaid business reply envelope, fax to: 414-459-8805, OR email to: recalls@genco.com