Allergan

URGENT DRUG RECALL
TAZORAC® GEL 0.05% 30g & 100g

May 10, 2016

Dear Valued Customer:

This is to advise you of Allergan's voluntary recall of *specific lots* of TAZORAC® (Tazarotene) GEL 0.05%. Detailed information for the affected products is provided in the Product Information section below.

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

PRODUCT INFORMATION

Lot	NDC	Product	Size	Dates Distributed	Exp. Date
84172	0023-8335-03	TAZORAC Gel 0.05%	30g	07/29/14 - 12/18/2014	FEB-2017
84173	0023-8335-10	TAZORAC Gel 0.05%	100g	04/30/2014-08/13/2014	FEB-2017

RECALL INFORMATION

Level:	***RETAIL***
Reason:	Results at the routine 24-month stability time point for lot # 84172 were slightly below regulatory specifications for Product Concentration and Content Uniformity. All other test parameters were within specification. Lots 84172 and 84173 were filled from the same bulk batch. As a precautionary measure, both lots are being recalled. *No other commercial lots of the TAZORAC® GEL 0.05% are connected with this recall.*
Health Hazard Assessment:	No adverse reaction reports or other indication of injuries have been reported for this issue or similar situations. The patient safety risk should be minimal relative to product concentration and content uniformity slightly below regulatory specifications. Adverse events are unlikely to occur because of product concentration and content uniformity being slightly below specification. Noticeable impact on efficacy and safety profile of the product is not anticipated.

ACTIONS REQUIRED

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

1. If you have inventory of the product lots in this recall, cease distribution and take precautions to quarantine the affected product inventory to prevent use.
2. Carry out a physical count of the affected product in your possession and record this data 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, 6101 North 64th Street, Milwaukee, WI 53218

5. ***If you have further distributed any of the affected product lots, we ask that you notify these customers. In your notification to your customers, please include our ACTIONS REQUIRED for returning the recalled merchandise and CONTACT INFORMATION.***

   We will issue a credit for product that you return that is associated with this recall. All product received that is not associated with this recall will be destroyed and credit will NOT be issued.

   Please contact GENCO Pharmaceutical Services if these recall actions are unclear.

CONTACT INFORMATION

Product Returns	**Adverse Events/Product Complaints**
Contact GENCO at: 855-633-1423, 7 am to 5 pm CST	Contact Allergan at: 1-800-433-8871, 8am - 8pm EST

FDA contact information for reporting adverse events/quality complaints:
Online at 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

Direct Accounts