

LUPIN SOMERSET

an Operating Division of Lupin Inc.

400 CAMPUS DRIVE, SOMERSET, NJ 08873
TEL: 908-603-6000



October 23, 2018

EXPANSION OF URGENT DRUG RECALL

Dear Valued Customer:

This is to inform you of an EXPANSION to the retail level for a product recall involving:

“Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle, NDC Number 43386-069-60, Lot# M16666 (Expiration date: 12/2018).”

See enclosed product label for ease in identifying the product.

This recall letter represents an update in scope to the original recall for the referenced product initiated on October 5, 2018. The recall was initiated due to an Out of Specification result for total impurities observed during stability analysis of Fluocinolone Acetonide Topical Solution, USP 0.01%, Lot# M16666, 60 ml bottle. The scope of this recall has been expanded to the retail level because the impurity is not yet identified and there may be a possibility that product use could cause irritation to the skin or that its efficacy may be reduced.

The investigation is ongoing to determine the unknown impurities (Results: 1.381%, Limit: NMT 1.0%) and the root cause of the out of specification results. Once the unknown impurities are identified, a Health Hazard Evaluation will be conducted. We have not received any adverse experience reports with this product. Using the drug is not likely to cause adverse health consequences.

We have distributed the recalled lot between 2/17/17 to 5/25/17 to the wholesalers/distributors, and retailers nationwide.

Immediately examine your inventory and quarantine product subject to recall. Wholesalers, distributors and retailers who have the effected product lot in their inventory should contact GENCO Pharmaceutical Services; a subsidiary of FedEx Supply Chain at 855-838-5783 Monday – Friday 7:30 am to 6:00 pm EST to return the product.

The lot number can be found on the side of the bottle.

This recall should be carried out to the **Retail Level**.

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Your assistance is appreciated and necessary to prevent possible consumption by the customer.

Please complete and return the enclosed response form as soon as possible.

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

1. Stop distribution and quarantine the subject lot numbers.
2. Carry out a physical count and record this data on the enclosed postage paid Business Card (BRC Reply) /Packing slip.
3. Mail the BRC within five (5) business days **even if you do not have the recalled product in your inventory**. To assure that we can account for all customers it is **imperative that you return this form even if you do not have product in stock**.
4. Attach the prepaid FedEx Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to GENCO at the address below;

If you have any questions, call

GENCO Pharmaceutical Services "a subsidiary of FedEx supply chain"
6101 North 64th Street
Milwaukee, WI 53218
Tel: 855-838-5783

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

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

Sincerely,

Scott Johnson
Director, Quality Assurance.
Lupin Somerset
400 Campus Drive

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Somerset, NJ 08873

NDC 43386-069-60

Fluocinolone Acetonide Topical Solution, USP

0.01%

For Topical Use Only
Not for Ophthalmic Use

Rx only
LUPIN

60 mL

Formula: Fluocinolone acetonide 0.1 mg/mL in a water-washable base of citric acid and polyethylene glycol.

Usual Dose: A exact amount should be gently massaged into the affected area two to four times daily, as needed.

See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Manufactured by
Novel Laboratories, Inc.
Somerset, NJ 08872

Manufactured for
Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202

LUP06000292
Rev 07/2016

Unvarnished Area
16mm x 55mm

CONTROL GROUP
Plated Packaging Solutions Pharmaceutical - Consumer - Consumer
 100 Industrial Blvd Somerset, NJ 08876 • controlgroup.com

proof date	7/28/2016
proof time	12:45:56 PM
operator	meureen.pedersen

Customer: **Lupin - Fluocinolone Acetonide 0.01% 60mL**

P.O. No #: **PENDING**

Job number: **NOVE 0203** Work Order: **33292**

Size: **1.75 x 4**

PROOFREAD INTERNALLY BY:	DATE:

Reviewed by:	Date
Submit Revised Proof:	Date
Proof Approved By:	Date

Inks:

NOTE: Proof colors do not represent exact PMS colors. Please check current PMS guide.

Web:

Roll direction chart

Roll Direction #4

Approved for:

	Yes	No	N/A
➔ Copy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
➔ Web layout (inc. eyemark)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
➔ Roll directions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C0296-02

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<p>The Standard Group 2415 Pleasant Dale Lansdale, Pennsylvania 19380-4077 Phone: 215-481-2700 Fax: 215-481-2707 www.standardgroup.com</p>	<p>QUALITY ASSURANCE: Our TSG Quality Assurance team has thoroughly reviewed this proof. We present this proof to you for your careful review. Please check to satisfy your requests for all components including the following: composition, color, size, spelling, punctuation, type face, font, left, and trapping. All PANTONE colors will be printed in the PMS BOOK or ink color shown. Colors to spot color should be indicated by the signal on the proof before sending the proof back to plant for production.</p>		7.25.16
	<p>Customer: Novel</p> <p>Job Description: Fluocinolone Acetonide</p> <p>Cad Designer: N15-C-01 CSR: Sharon R.</p>		<p>CLIENT APPROVAL</p> <p>Signature: _____</p> <p>Date: _____</p> <p>Signed approval releases Graphics into production</p>
<p>1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd <input type="checkbox"/> 4th <input type="checkbox"/> 5th <input type="checkbox"/> 6th <input type="checkbox"/> 7th <input type="checkbox"/> 8th <input type="checkbox"/></p>			<p>SFC Approvals</p>

