



Lupin Pharmaceuticals, Inc.

January 28, 2019

MANUFACTURED BY:

Lupin Limited
Pithampur (M.P.) 454 775 INDIA

MANUFACTURED FOR:

Lupin Pharmaceuticals, Inc.
111 South Calvert Street
Baltimore, Maryland 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – RETAIL LEVEL

Bimatoprost Ophthalmic Solution, 0.03%

Lupin Pharmaceuticals, Inc. is voluntarily recalling lot **H804506, Expiry June 2020, H803555 Expiry April 2020, H805394 Expiry August 2020, H804112 Expiry May 2020 and H803220 Expiry March 2020 of Bimatoprost Ophthalmic Solution, 0.03%** to the retail level. These product lots are being recalled, due to the out of specification results observed in any other individual impurity and total impurities.

Its unlikely that a slight increase in the levels of any other individual impurity and total impurities could lead to serious adverse reactions.

The recalled lots were distributed between September 6, 2018 and January 14, 2019 to wholesalers and mail order pharmacy nationwide.

Immediately examine your inventory and quarantine the product lots subject to recall. Wholesalers and distributors should forward this notification to the retailers. Wholesalers and distributors who have the affected product lots in their inventory should contact GENCO Pharmaceutical Services at 1-866-307-0012 Monday – Friday 7:30 am to 6:00 pm EST. For reimbursement, please have the recalled lots returned to GENCO on or before April 15, 2019. The lot number can be found on the side of the bottle.

Bimatoprost Ophthalmic Solution, 0.03% is supplied as below:

Strength	Description
0.03%	Bimatoprost Ophthalmic Solution, 0.03% is supplied as a clear, colorless transparent liquid packed in a 5mL LDPE opaque bottle which is closed with LDPE white nozzle and then with Turquoise colored HDPE cap. NDC 68180-429-02 (5mL) and 68180-429-03 (7.5mL)



Lupin Pharmaceuticals, Inc.

Product label:

NDC 68180-429-02

Bimatoprost Ophthalmic Solution

0.03%

FOR USE IN THE EYES ONLY

Rx only STERILE

LUPIN 5 mL

Each mL of solution contains:
Active: bimatoprost 0.03% (0.3 mg)
Preservative: benzalkonium chloride NF 0.005%
Usual Dosage. Refer to package insert.
Storage: Store at 2 to 25°C (36 to 77°F).

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M.L. 28/6/2010 235959

6818042902

8 x 15.5 mm

LOT NO. EXP

NDC 68180-429-03

Bimatoprost Ophthalmic Solution

0.03%

FOR USE IN THE EYES ONLY

Rx only STERILE

LUPIN 7.5 mL

Each mL of solution contains:
Active: bimatoprost 0.03% (0.3 mg)
Preservative: benzalkonium chloride NF 0.005%
Usual Dosage. Refer to package insert.
Storage: Store at 2 to 25°C (36 to 77°F).

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8 x 15.5 mm

LOT NO. EXP

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

A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY CARD AND A PREPAID FEDEX AUTHORIZED RETURN SERVICESM SHIPPING LABEL WILL BE MAILED WITHIN (5) BUSINESS DAYS. THE REPLY CARDS AND RECALLED PRODUCT SHOULD BE SHIPPED TO:

Attention:

GENCO Pharmaceutical Services "a subsidiary of FedEx supply chain"
 6101 North 64th Street
 Milwaukee, WI 53218
 Tel: 1-866-307-0012



Lupin Pharmaceuticals, Inc.

We appreciate your immediate attention to this matter. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Anurag Mishra
Sr. Manager, Quality
Lupin Pharmaceuticals, Inc.