



# Lupin Pharmaceuticals, Inc.

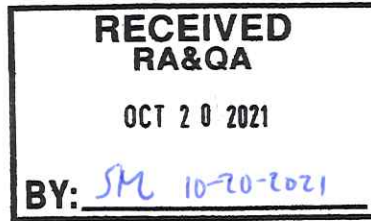
October 20, 2021

**MANUFACTURED BY:**

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

**MANUFACTURED FOR:**

Lupin Pharmaceuticals, Inc.  
Baltimore, MD 21202  
United States



Dear Healthcare Partner,

**URGENT: DRUG RECALL – RETAIL LEVEL**

**Gatifloxacin Ophthalmic Solution, 0.5%**

Lupin Pharmaceuticals, Inc. is voluntarily recalling lot **H002512** Expiry **March 2022** of Gatifloxacin Ophthalmic Solution, 0.5% to **retail** level. Out of an abundance of caution, this product lot is being recalled due to an out of specification result observed in a water loss test at the 9-month long term stability time point.

Increased water loss value might affect the assay content, evaporation of water from this liquid preparation may alter drug concentration.

The recalled lot was distributed between December 22, 2020 and March 1, 2021 to wholesalers, distributors, and super markets (food) nationwide.

Immediately examine your inventory and quarantine the product lot subject to recall. Wholesalers and distributors should forward this notification to retailers. Wholesalers and distributors who have the affected product lot in their inventory should contact Inmar Rx Solutions, Inc. at (855) 824-9449 Monday – Friday 9:00 am to 5:00 pm EST. For reimbursement, please have the recalled lot returned to Inmar Rx Solutions, Inc. on or before January 31, 2022. The lot number can be found on the side of the bottle.

**Gatifloxacin Ophthalmic Solution, 0.5% is supplied as:**

| Strength | NDC's        | Pack  | Description                                                                                                                                                                                                                                                            |
|----------|--------------|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0.5%     | 68180-435-01 | 2.5mL | Gatifloxacin Ophthalmic Solution, 0.5% is yellow (pale yellow) sterile solution in a 5 mL white, low-density polyethylene (LDPE) bottle fitted with a white low-density polyethylene (LDPE) nozzle and sealed with a tan colored high-density polyethylene (HDPE) cap. |



# Lupin Pharmaceuticals, Inc.

**RECEIVED  
RA&QA**

OCT 20 2021

BY: *SM 10-20-2021*

Product label:

|                                                   |                                                                              |                                                                                                                                                                                                              |                 |                       |
|---------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------------|
| <br><b>LUPIN</b>                                  | <b>NDC 68180-435-01</b><br><b>Gatifloxacin</b><br><b>Ophthalmic Solution</b> | Each mL of solution contains<br>Active: gatifloxacin 0.5% (5 mg)<br>Preservative: benzalkonium chloride NF 0.005%<br><b>Usual Dosage:</b> Refer to package insert.<br><b>Storage:</b> Protect from freezing. | <br>68180435013 | OPZ Area<br>8 x 10 mm |
|                                                   | <b>0.5%</b>                                                                  | Manufactured by:<br><b>Lupin Limited</b><br>Pithampur (M.P.) 454 775, INDIA                                                                                                                                  |                 |                       |
| <b>FOR USE IN THE EYES ONLY</b><br><b>Rx only</b> |                                                                              | STERILE<br><b>LUPIN</b>                                                                                                                                                                                      | 260028<br>      | LOT NO.<br>EXP.       |

This recall should be carried out to the retail level.

**A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY FORM WILL BE MAILED WITHIN (5) BUSINESS DAYS. THE REPLY FORMS SHOULD BE RETURNED TO INMAR THROUGH MAIL/EMAIL/FAX. ONCE RECEIVED AN RA AND NEEDED BOX LABELS WILL BE PROVIDED.**

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

1. **Distributors/Pharmacies** – Immediately examine your inventory, quarantine and discontinue distribution of above lot.
2. **Distributors** – Complete the enclosed Business Response Form (BRF) even if you do not have any product on hand.
3. **Distributors** – Please pass this Recall Notice **ONLY** to pharmacies that received recalled product lot.
4. **Pharmacies** – If you have units of the affected product/lot in inventory, please contact Inmar Pharmaceuticals Services at (855) 824-9449 to receive a Business Recall Response form or acquire it from [clsnetlink.com](http://clsnetlink.com).
5. Business Recall Response Form (BRF) can be submitted by any of these methods.  
**Fax:** 817-868-5362  
**Email:** [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)  
**Address:** Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101
6. **Distributors/Pharmacies** – Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.

**Upon receipt of the completed BRF, a return kit will be sent including an RA form and necessary box labels.**

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



# Lupin Pharmaceuticals, Inc.

Sincerely,

Anurag  
Mishra

Digitally signed by  
Anurag Mishra  
Date: 2021.10.20  
13:02:39 -04'00'

Anurag Mishra

Associate Director, Quality