FDC Limited

MANUFACTURERS & EXPORTERS OF FOODS, DRUGS & CHEMICALS

URGENT VOLUNTARY DRUG RECALL

Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL,

Batches 083L111 & 084A032

January 04, 2025

Marketing and Distribution Firm:	**Manufacturing and Recalling Firm**
Leading Pharma, LLC. 3 Oak Road, Fairfield, New Jersey 07004	FDC Limited B-8, MIDC Industrial Area Waluj, Aurangabad, Maharashtra, India 431 136

Dear Leading Team,

FDC Limited, is initiating a voluntary recall for **Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL,** batch number **083L111 and 084A032** (ANDA 077568) manufactured at FDC Limited located in Maharashtra, India and marketed by Leading Pharma, LLC (A sole distributer for this product in USA). Our records indicate that you have purchased this product, during the dates it was shipped.

This voluntary recall is based on complaints received from patients wherein it is reported that the patients are unable to get the product solution out of the bottle as the spike of the cap was lodged in the nozzle of product bottle.

FDC Limited has conducted preliminary investigation and has performed health hazard assessment. This assessment concluded that it is unlikely that this issue can cause any adverse health consequences to the patients and no long-term risk can be stipulated.

We have shipped this product to you details of shipments are as below;

Product Name	NDC(s)	Lot(s) /	Exp. Date	Consignee	Quantity Shipped to Distributor	Shipping dates
Ciprofloxacin Ophthalmic Solution USP 0.3%, 5 mL	69315-308-05	083L111	11/2025	Leading Pharma, LLC	67656 Units	02/08/2024
Ciprofloxacin Ophthalmic Solution USP 0.3%, 5 mL	69315-308-05	084A032	12/2025	Leading Pharma, LLC	68616 Units	02/08/2024

Action to be taken by Leading Pharma:

1. Immediately examine your inventory and quarantine the product subjected to recall.
2. This recall should be carried out to the retail level.
3. Please carryout a physical count and record this data on the enclosed response form.
4. Even if you don't have the recalled product, please email the completed response form to rxrecalls@inmar.com or through Fax: 1-817-868-5362.
5. Upon receipt of your confirmation, Inmar Intelligence will create a Postage Paid Product Return label to return the product.
6. Return the recalled product, noting "RECALLED PRODUCT" on the accompanying paper work and using the prepaid shipper label to

Address: Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

- In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
- If they have any questions regarding the return of this recall product, please have them call 877-560-2579
- This action applies only Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL, (NDC 69315-308-05) batch number 083L111 and 084A032. No other batches of Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL, NDC Code 69315-308-05 are affected by this recall.

1. If you have any medical questions regarding this recall, please contact Leading Pharma's, LLC drug safety group at 973-276-9600 (9:00 am - 5:00 pm EST).

2. For adverse reactions or quality problems experienced with the use of this product, please contact Leading Pharma's at 844-740-7500 (8:30 am - 5:00 pm EST) or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax:

   To complete and submit the report Online: www.fda.gov/medwatch/report.htm

For regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

- If you have any general questions regarding the return of this product, please contact please have them call 877-560-2579.

We regret any inconvenience caused and appreciate your immediate cooperation.

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

Thank you,

Sandip Chougule
Digitally signed by Sandip Chougule
Date: 2025.01.04 11:01:44 +05'30'

Name:- Sandip B. Chougule
Title :- Vice President - Corporate Quality Assurance

FDC LTD.
C/3, Sky Vistas, Near Versova Police Station,
106-A J.P.Road, D.N.Nagar, Andheri (West),
Mumbai - 400 053"

Enclosure :- Voluntary Recall Response Form.

FDC Limited

MANUFACTURERS & EXPORTERS OF FOODS, **DRUGS & CHEMICALS**

Product Label

Product Carton for Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL

Each mL contains: Active: 3.5 mg ciprofloxacin hydrochloride equivalent to ciprofloxacin base 3 mg. **Preservative:** benzalkonium chloride 0.006% **Inactives:** sodium acetate, acetic acid, mannitol, edetate disodium, hydrochloric acid and/or sodium hydroxide (to adjust pH) and water for injection.

PRECAUTIONS:
Do not touch dropper tip to any surface, as this may contaminate the solution.

USUAL DOSAGE
Read enclosed insert.

FOR TOPICAL OPHTHALMIC USE ONLY

Retain in carton until contents are used and protect from light

MODE OF USE


Snap off the dust cover by turning it clockwise to break the seal


Pull off the dust cover


Unscrew the tan coloured cap


Dispense the drops with gentle pressure. Place back the tan coloured cap

***Storage** : Store at 25°C (77° F); excursions permitted 15°-30°C (59°-86°F) [See USP controlled room temperature]*

Distributed by:
Leading Pharma, LLC.
Fairfield, NJ07004

Manufactured by:
FDC Limited
B-8, MIDC Industrial Area,
Waluj, Aurangabad - 431 136,
Maharashtra, India.

Mfg. Lic. No. 1032

N 3 69315 30805 9

NDC 69315-308-05

CIPROFLOXACIN OPHTHALMIC SOLUTION USP 0.3% as base

Sterile

5 mL **Rx Only**

LEADING PHARMA

Bottle label for Ciprofloxacin Ophthalmic Solution USP 0.3% 5 mL

Lot:

Exp.:

Batch code area
19 (L) x 5.5 (H) mm

LEADING PHARMA

Retain in carton until contents are used and protect from light.
Mfg. Lic. No. 1032

5 mL

NDC 69315-308-05 **Rx Only**

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FOR TOPICAL OPHTHALMIC USE ONLY
Distributed by: Leading Pharma, LLC., Fairfield, NJ07004
Manufactured by: FDC Limited
B-8, MIDC Industrial Area,
Waluj, Aurangabad - 431 136,
Maharashtra, India.

20000007150

N 3 69315 30805 9

FDC Limited

MANUFACTURERS & EXPORTERS OF FOODS, DRUGS & CHEMICALS

[CIPROFLOXACIN OPHTHALMIC SOLUTION USP 0.3%,]
[RETAIL Level Recall]
[Date: TBD]
[Notice # TBD]

VOLUNTARY RECALL RESPONSE FORM

Date Form Completed _____

Please fill out this form completely, by doing so this will acknowledge that you have read and understand the recall notice and have taken the appropriate action. Once complete please return your response form by any one of these means to Inmar Intelligence, Attn: Recall Team: EMAIL: rxrecalls@inmar.com FAX: 1-817-868-5362

This Response Form is for (Check One)	☐ **Direct Customer (Purchased Directly from MANUFACTURER)** ☐ **Non-Direct Customer**
Customer/Store Name:	
*DEA #: ***DEA # is required in order to process your form***	Debit Memo # (If Applicable)
Address:	City/State/Zip
Contact Name (please print):	Email Address: Telephone #: Fax #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(Complete Below Table)** **OR** ☐ I ***do not*** have stock of the recalled item(s).

Direct Customers

Does your response include **all** your DC locations? ☐ YES ☐ NO

Have you notified your customers of this recall down to the appropriate level? ☐ YES ☐ NO

Non-Direct Customers

Name of Wholesaler/Distributor and address the product(s) in this recall were purchased from (Please include DEA):

☐ ***I have quarantined and listed in the table below the quantity of recall units I will be returning to Inmar Intelligence***

NDC Code 69315-308-05 Batch number 083L111 and 084A032 If additional space is needed please make copies of this form.

NDC	Lot #	Exp. Date	Qty. Case to be returned	Qty. Sealed to be returned	Qty. Partial Bottles to be returned
69315-308-05	083L111	11/2025			
69315-308-05	084A032	12/2025			

Any Adverse Events Associated with this recalled product? ☐ No ☐ Yes (if yes please attach additional sheet and explain)

Please indicate the number of (additional) shipping labels that you need to return the recalled product(s): _____