Sun Pharmaceutical Industries, Inc

URGENT: DRUG RECALL
Lidocaine Ointment USP, 5.0%

Reissuing due to change in recall depth, please perform to RETAIL LEVEL

September 14, 2026

Dear Valued Customer,

This notice is to inform you of a product recall involving, **Lidocaine Ointment USP, 5.0% 50g jar**; see enclosed product label for ease in identifying the product at the retail level. **(This is a marketed product under the Taro Pharmaceutical label).**

Product Name	Package Description	NDC#	Lot#	Expiration Date
Lidocaine Ointment USP, 5.0%	50g jar	51672-3008-5	AD48154	4/30/2027

This recall has been initiated in response to Out of Specification, (OOS) / slightly lower than the specification results in Assay during content uniformity analysis at the 24- month long term stability station, at (25°C, 60%RH).

The Health Hazard Evaluation concluded that as this product is intended for temporary symptomatic relief, this slight decrease in potency, approximately 1.4% below the lower specification limit may result in a minor reduction in the product's local anesthetic and analgesic effectiveness.

The lot complied with all of the established product quality specifications at the time the product was released for distribution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on February 10, 2025.

Immediately examine your inventory and quarantine product subject to the recall. In addition, if you have further distributed this product, please identify your **retail** customers and notify them at once of this product recall. Your notification to your **retail** customers may be enhanced by including a copy of this recall letter.

Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

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

If you have any questions or return the enclosed response form contact Inmar, Inc. at Rxrecalls@Inmar.com or call **877-213-6676** Monday to Friday from 8:30 am to 5:00 pm (EST).

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

Your assistance is appreciated and necessary to prevent patient harm.

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

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

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

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

Aster Amanuel

Signed by:
Aster Amanuel 9/14/2026
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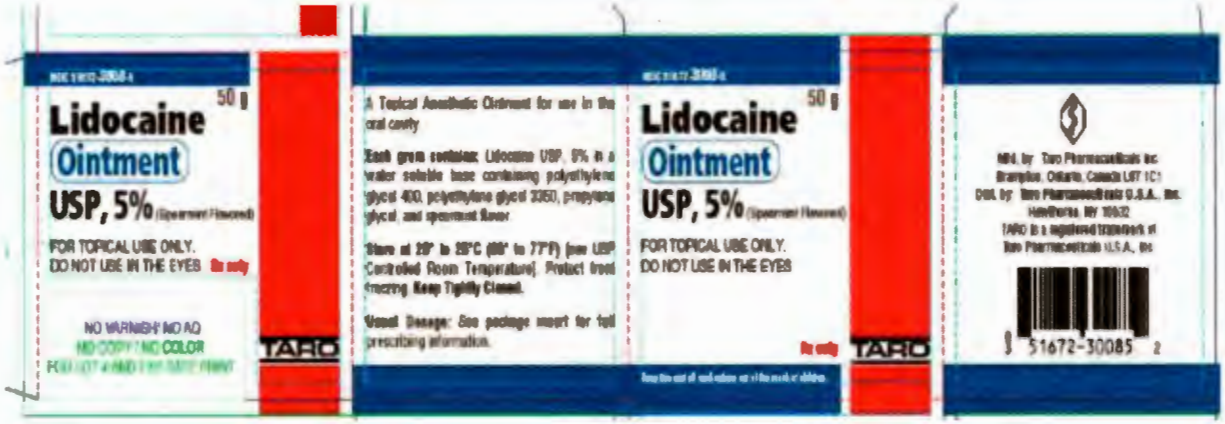
Sun Pharmaceutical Industries, Inc.
Manager, Quality Compliance

For return of affected product, please email Rxrecalls@Inmar.com or call **877-213-6676**

Enclosure:

Lidocaine Ointment USP, 5.0% _ Label



Sun Pharmaceuticals Industries, Inc.

URGENT: DRUG RECALL – RESPONSE FORM

Lidocaine Ointment USP, 5.0%

(*Reissuing due to change in recall depth, please perform to Retail Level)

(This is a marketed product under the Taro Pharmaceutical label)

*Retail Level

9/14/2026

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name:	DEA#:

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	

DEBIT MEMO# (If unsure, leave blank):

Wholesaler Information if not directly purchased from Sun Pharma:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

- ☐ I confirm that all locations that received the impacted products have been notified to the **Retail level** _____(Initial and date)
- ☐ I do not have any stock of the recalled items. **OR**

  ☐ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s). Please indicate the # of needed box labels_____.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Input Total Number of Units
Lidocaine Ointment USP, 5.0%	50g jar	51672-3008-5	AD48154	4/30/2027	

If you have any questions regarding this form or product return please contact Inmar Inc. at Rxrecalls@Inmar.com or call **877-213-6676** Monday to Friday from 8:30 am to 5:00 pm (EST).

Please fax this form to: 1-817-868-5362 or E-mail: Rxrecalls@Inmar.com