



Sun Pharmaceutical Industries, Inc

URGENT: DRUG RECALL
Retail Level
Tretinoin Cream, 0.05%

September, 25, 2026

Dear Valued Customer,

This notice is to inform you of a product recall involving, **Tretinoin 0.05% Cream, 20 g and 45 g**; see enclosed product label for ease in identifying the product at the retail level. **(This is a marketed product under the Taro Pharmaceutical label and NorthStar label).**

Product Name	Package Description	NDC#	Lot#	Expiration Date
Tretinoin 0.05% Cream	45G tube	51672-1394-9	AD96184	12/31/2026
Tretinoin 0.05% Cream	45G tube	16714-249-02	AD96183	12/31/2026
Tretinoin 0.05% Cream	20 G tube	51672-1394-0	AD96196	12/31/2026

This recall has been initiated in response to Out of Specification, (OOS), result for impurity, (Impurity-2), during analysis at the 18- month long term stability station, at (25°C, 60%RH).

The Health Hazard Evaluation concluded *“the impurity is considered as non-mutagenic. All other critical quality parameters are within specification limit including assay at the 18-month time point. Therefore, it can be concluded that the out of specification result observed for the known impurity, (Impurity 2), against the specification limit of NMT 2.5%, is unlikely to pose any serious safety concern in patients other than the known safety profile of the drug.”*

The lots 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 9/2/2025.

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 **866-652-7566** 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.

Regards,
Aster Amanuel

Signed by:

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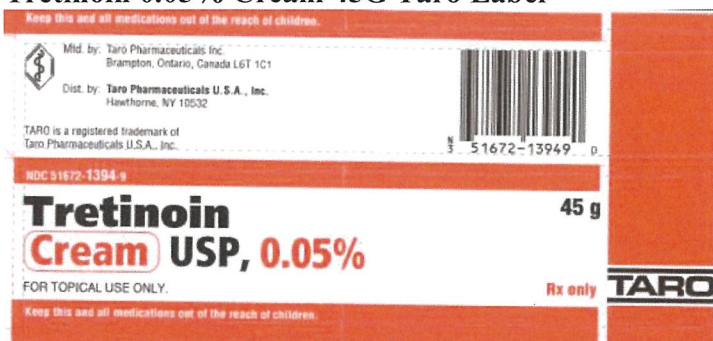
9/25/2026

Sun Pharmaceutical Industries, Inc.
Manager, Quality Compliance

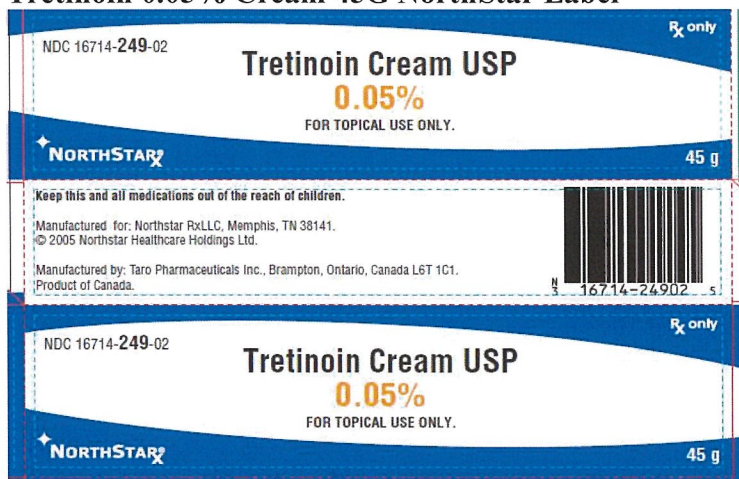
For return of affected product, please email Rxrecalls@Inmar.com or call **866-652-7566**

Enclosure:Product Label:

Tretinoin 0.05% Cream 45G Taro Label



Tretinoin 0.05% Cream 45G NorthStar Label



Tretinoin 0.05% Cream 20G Taro Label



Sun Pharmaceuticals Industries, Inc.
URGENT: DRUG RECALL – RESPONSE FORM (Retail Level)
Tretinoin Cream, 0.05%



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

9/25/2026

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
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Tretinoin 0.05% Cream	45G tube	16714-249-02	AD96183	12/31/2026	
Tretinoin 0.05% Cream	20 G tube	51672-1394-0	AD96196	12/31/2026	

If you have any questions regarding this form or product return please contact Inmar Inc. at Rxrecalls@Inmar.com or call **866-652-7566** 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

RCL280-26 / N131530