



Sun Pharmaceutical Industries, Inc

URGENT: DRUG Market Withdrawal
Wholesale Level
Tretinoin Cream, 0.05% & 0.1%

September , 25, 2026

Dear Valued Customer,

This notice is to inform you of a product Market Withdrawal involving, **Tretinoin 0.05% and Tretinoin 0.1%, 20 g and 45 g**; see enclosed product label for ease in identifying the product market withdrawal at the wholesale level.

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

Product Name	Package description	NDC	Lot#	Exp. Date
Tretinoin 0.05% Cream	Tube 20gm	16714-249-01	AD84626	9/30/2026
Tretinoin 0.05% Cream	Tube 20gm	51672-1394-0	AD84627	9/30/2026
Tretinoin 0.05% Cream	Tube 45gm	16714-249-02	AD84628	9/30/2026
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD84629	9/30/2026
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD84630	9/30/2026
Tretinoin 0.1% Cream	Tube 20gm	16714-250-01	AD85409	9/30/2026
Tretinoin 0.1% Cream	Tube 20gm	51672-1395-0	AD85410	9/30/2026
Tretinoin 0.1% Cream	Tube 45gm	16714-250-02	AD85411	9/30/2026
Tretinoin 0.1% Cream	Tube 45gm	51672-1395-9	AD85412	9/30/2026
Tretinoin 0.05% Cream	Tube 45gm	16714-249-02	AD90538	10/31/2026
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD90539	10/31/2026
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD96186	12/31/2026
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD96193	12/31/2026
Tretinoin 0.05% Cream	Tube 20gm	16714-249-01	AD96195	12/31/2026
Tretinoin 0.1% Cream	Tube 20gm	16714-250-01	AD96197	12/31/2026
Tretinoin 0.1% Cream	Tube 45gm	16714-250-02	AD96201	12/31/2026
Tretinoin 0.1% Cream	Tube 45gm	51672-1395-9	AD96202	12/31/2026

This Market Withdrawal is being performed as a precautionary measure. It was triggered in response to Out of Specification, (OOS), result for a known Impurity, Impurity-2, during analysis at the 18- month long term stability station, at (25°C, 60%RH), for another lot of Tretinoin 0.05% Cream, that is not in this list.



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 May 6, 2025

Immediately examine your inventory and quarantine product subject to the Market Withdrawal. In addition, if you have further distributed this product, please identify your **wholesale** customers and notify them at once of this product Market Withdrawal. Your notification to your **wholesale** customers may be enhanced by including a copy of this Market Withdrawal 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 **855-337-4233** Monday to Friday from 8:30 am to 5:00 pm (EST).

This Market Withdrawal should be carried out to the wholesale level.

Your assistance is appreciated and necessary.

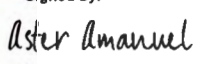
For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

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 Market Withdrawal is being made with the knowledge of the Food and Drug Administration.

Aster Amanuel

Signed by:  9/25/2026
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Sun Pharmaceutical Industries, Inc.
Manager, Quality Compliance

For return of affected product, please email Rxrecalls@Inmar.com or call **855-337-4233**

Enclosure:Product Label:
Tretinoin 0.05% Cream 45G Taro Label

Keep this and all medications out of the reach of children.

Mfg. by: Taro Pharmaceuticals Inc.
 Brampton, Ontario, Canada L6T 1C1

Dist. by: Taro Pharmaceuticals U.S.A., Inc.
 Hawthorne, NY 10532

TARO is a registered trademark of
 Taro Pharmaceuticals U.S.A., Inc.

NDC 51672-1394-9

Tretinoin
Cream USP, 0.05% 45 g

FOR TOPICAL USE ONLY. Rx only **TARO**

Keep this and all medications out of the reach of children.

Tretinoin 0.05% Cream 20G Taro Label

Keep this and all medications out of the reach of children.

Mfg. by: Taro Pharmaceuticals Inc.
 Brampton, Ontario, Canada L6T 1C1

Dist. by: Taro Pharmaceuticals U.S.A., Inc.
 Hawthorne, NY 10532

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 Taro Pharmaceuticals U.S.A., Inc.

NDC 51672-1394-0

Tretinoin
Cream USP, 0.05% 20 g

FOR TOPICAL USE ONLY. Rx only **TARO**

Keep this and all medications out of the reach of children.

Tretinoin 0.1% Cream 20G Taro Label

NDC 51672-1395-0

Tretinoin
Cream USP, 0.1% 20 g

FOR TOPICAL USE ONLY. Rx only **TARO**

Keep this and all medications out of the reach of children.

Mfg. by: Taro Pharmaceuticals Inc.
 Brampton, Ontario, Canada L6T 1C1

Dist. by: Taro Pharmaceuticals U.S.A., Inc.
 Hawthorne, NY 10532

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 Taro Pharmaceuticals U.S.A., Inc.

NDC 51672-1395-0

Tretinoin 0.1% Cream 45G Taro Label

NDC 51672-1395-9

Tretinoin
Cream USP, 0.1% 45 g

FOR TOPICAL USE ONLY. Rx only **TARO**

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 Brampton, Ontario, Canada L6T 1C1

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 Hawthorne, NY 10532

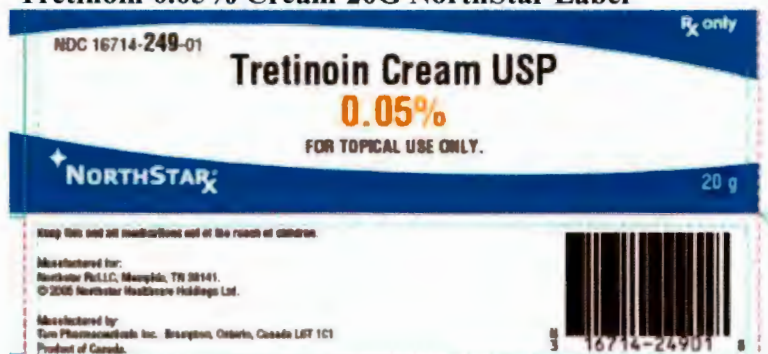
TARO is a registered trademark of
 Taro Pharmaceuticals U.S.A., Inc.

NDC 51672-1395-9

Tretinoin 0.05% Cream 45G NorthStar Label



Tretinoin 0.05% Cream 20G NorthStar Label



Tretinoin 0.1% Cream, 20 g



Tretinoin 0.1% Cream, 45 g



Sun Pharmaceuticals Industries, Inc.
URGENT: DRUG Market Withdrawal – RESPONSE FORM (Wholesale Level)
Tretinoin Cream, 0.05% & 0.1%



(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 market withdrawal 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 **Wholesale level** _____ (Initial and date)
- ☐ I do not have any stock of the market withdrawal items. **OR**
- ☐ I have quarantined and listed in the box below the quantity of market withdrawal 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#	Exp. Date	Input Total Number of Units
Tretinoin 0.05% Cream	Tube 20gm	16714-249-01	AD84626	9/30/2026	
Tretinoin 0.05% Cream	Tube 20gm	51672-1394-0	AD84627	9/30/2026	
Tretinoin 0.05% Cream	Tube 45gm	16714-249-02	AD84628	9/30/2026	
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Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD84630	9/30/2026	
Tretinoin 0.1% Cream	Tube 20gm	16714-250-01	AD85409	9/30/2026	
Tretinoin 0.1% Cream	Tube 20gm	51672-1395-0	AD85410	9/30/2026	
Tretinoin 0.1% Cream	Tube 45gm	16714-250-02	AD85411	9/30/2026	
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Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD96186	12/31/2026	
Tretinoin 0.05% Cream	Tube 45gm	51672-1394-9	AD96193	12/31/2026	
Tretinoin 0.05% Cream	Tube 20gm	16714-249-01	AD96195	12/31/2026	
Tretinoin 0.1% Cream	Tube 20gm	16714-250-01	AD96197	12/31/2026	
Tretinoin 0.1% Cream	Tube 45gm	16714-250-02	AD96201	12/31/2026	
Tretinoin 0.1% Cream	Tube 45gm	51672-1395-9	AD96202	12/31/2026	

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URGENT: DRUG Market Withdrawal – RESPONSE FORM (Wholesale Level)
Tretinoin Cream, 0.05% & 0.1%



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

9/25/2026

If you have any questions regarding this form or product return please contact Inmar Inc. at Rxrecalls@Inmar.com or call **855-337-4233** 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