Sun Pharmaceutical Industries, Inc

URGENT: DRUG RECALL

Nystatin Cream

RETAIL LEVEL

Sep 10, 2026

Dear Valued Customer,

This notice is to inform you of a product recall involving, **Nystatin Cream**; 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
Nystatin Cream 100,000 Units/G	15 g	51672-1289-1	AD49605	05/31/2027
	30 g	51672-1289-2	AD49606	05/31/2027

This recall has been initiated in response to a quality complaint report for watery texture for Batch AD49605. During homogeneity testing of the 24-month retain sample, Batch AD49605, an Out-of-Specification (OOS) for phase separation was identified. Batch AD49606 is from the same bulk batch as AD49605 and included in the recall.

Based on the Health Hazard Evaluation,
"The watery texture and hardened back end of the Nystatin Cream tube are visible to the naked eye and likely to be identified by the user prior to application; the probability of inadvertent application of the affected cream is therefore considered unlikely.
The observed separation into a free-flowing liquid phase and a hardened cream phase indicates a loss of physical stability and product uniformity. This may result in inconsistent distribution of the active ingredient, subtherapeutic dosing and reduced clinical effectiveness."

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

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on December 10, 2024.

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 **855-319-3840** 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.

Xiomara Lesniak

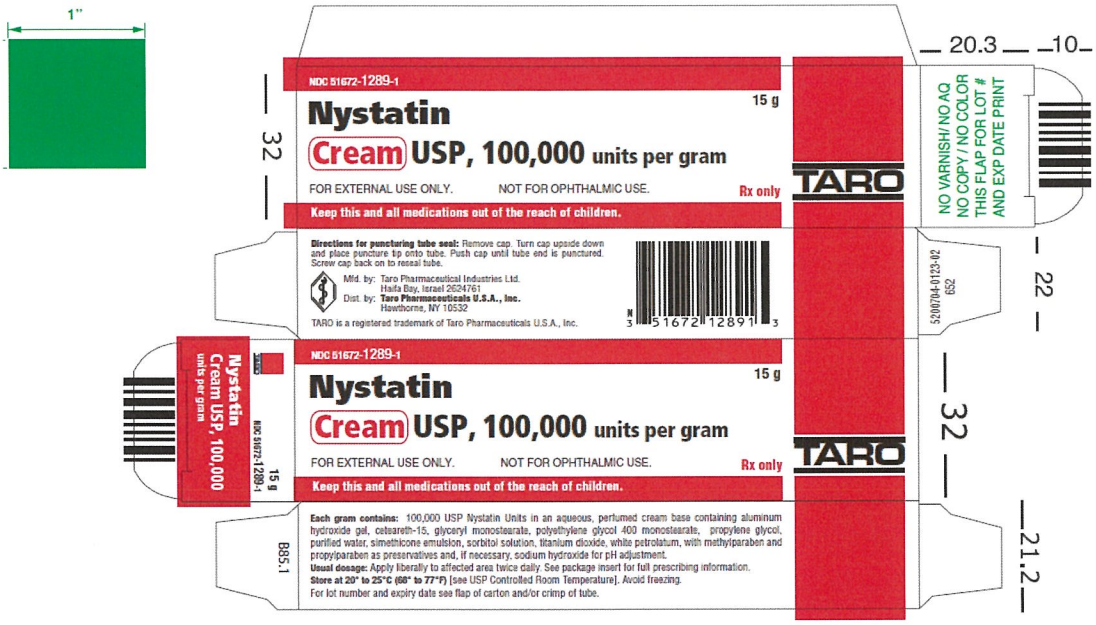
Xiomara Lesniak

Sun Pharmaceutical Industries, Inc.
Sr Manager, Quality Compliance

For return of affected product, please email Rxrecalls@Inmar.com or call **855-319-3840**

Enclosure:

Nystatin Cream _ Label
NDC: 51672-1289-1



NDC: 51672-1289-2

Sun Pharmaceuticals Industries, Inc.
URGENT: DRUG RECALL – RESPONSE FORM
Nystatin Cream

RETAIL LEVEL

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

Retail Level
09/10/2026

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
Nystatin Cream USP 100,000 Units/G	15 g	51672-1289-1	AD49605	05/31/2027	
	30 g	51672-1289-2	AD49606	05/31/2027	

If you have any questions regarding this form or product return please contact Inmar Inc. at Rxrecalls@Inmar.com or call **855-319-3840** 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