Padagis®

# URGENT: DRUG RECALL

**Please Read Immediately**

June 23, 2026

Dear Valued Customer,

Padagis US LLC is initiating a retail / pharmacy level recall for one batch of **Nystatin Cream 15 g** in the marketplace. Customers that may have further distributed this product are requested to contact their customers and notify them immediately of this product recall.

The batch, lot number 205060, is being recalled due to low out of specification assay results performed during long-term stability testing. There have been no associated adverse event or lack of efficacy reports for the affected batches. Use of the affected product is not expected to pose a significant patient safety risk. See enclosed product label for ease in identifying the product at the retail level.

This action is being taken with the knowledge of the Food and Drug Administration and is being issued to the retail level. We are asking for returns of the affected batches from all warehouse and retail locations. Please return the enclosed card immediately providing the requested information.

We deeply regret any inconvenience and appreciate your assistance with this recall. Please refer to the Recall Notification Details document for aid in returning product. Padagis is partnering with Inmar, a leading organization in conducting recalls. Please email Inmar at rxrecalls@inmar.com or call Recall Services at 855-937-2931 (9 am to 5 pm EST Monday through Friday) for assistance in returning product. If we can provide any additional information or assistance, please contact the recall coordinator, Brock Gunderson, at Recall@padagis.com.

Sincerely,

David Tyree
Sr. Vice President of Global Quality
Padagis US LLC

Padagis®

# Recall Notification Details
## Nystatin Cream 15 g
## (Retail Level)
June 2026

| | |
|---|---|
| **Product** | Product: RX NYSTATIN CRM 100,000U/G 15G<br>NDC: 45802-0059-35<br>Strength: 100,000 U / g<br>Package Size: 15 g tube<br>Batch Numbers 205060<br>Manufactured By: Padagis Israel Pharmaceuticals<br><br>Product Distributed between: 11/14/2025 – 5/15/2026 |
| **Reason** | The batch, lot number 205060, is being recalled due to low out of specification assay results performed during long-term stability testing.<br><br>Health Hazard: There is potential for a slight change regarding the drug's overall efficacy. There have been no associated adverse event or lack of efficacy reports for the affected batches and there is no risk to patient safety observed at this time. |
| **Action** | 1. If you have the affected lot numbers of the recalled product in your stock, please discontinue further distribution, quarantine the affected product and return all units to: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.<br>2. 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.<br>3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at 1-817-868-5362 or email it to rxrecalls@inmar.com. Even if you do not possess any inventory of the lot being recalled, we would appreciate it if you could still fill out and return the "PRODUCT RECALL RESPONSE FORM".<br>4. Effectiveness Check: The FDA requires Padagis to verify notifications to determine the effectiveness of this recall. Padagis will begin making these effectiveness checks by email or phone within four weeks via Inmar. |
| **Credit** | Credit will be issued for product returned using the Inmar provided RA# and matching the product's description above. Credit will only be issued for product from the affected batch returned within 60 days. Credit will be issued against a Padagis customer deduction.<br><br>Credit may be denied if the RA# is not properly referenced at the time of the return or when the customer deduction is taken. |
| **Other Information** | **This recall is only for the product and batch listed above.** Notifications are being sent out to all the accounts that purchased this product from Padagis US LLC.<br><br>For medical questions contact Padagis Call Center at 1-866-634-9120 or Consumer.Support@Padagis.com<br><br>For Product returns and Response form questions: rxrecalls@inmar.com or calling 855-937-2931 (office hours 9am to 5pm EST Monday through Friday).<br><br>We sincerely regret any inconvenience caused by this action and appreciate your immediate attention and cooperation. |

**Padagis**
**URGENT: DRUG RECALL – RESPONSE FORM**
**RX NYSTATIN CRM 100,000U/G 15G**
**Retail Level**
**6/18/2026**

**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 Padagis:**

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

**I have checked my stock and:**

- ☐ 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 | Total Quantity of Units (full and partial bottles/cartons) |
|---|---|---|---|---|---|
| Nystatin Cream 15 g | 15 g cream / tube | 45802-0059-35 | 205060 | 09/30/2027 | |

If you have any questions regarding this form or product return please contact Inmar at 855-937-2931 (office hours 9am to 5pm EST Monday through Friday).

**Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com**

**Event ID: RCL164-26 / N131494**