



## **URGENT: DRUG RECALL**

### **Niacin Extended-Release Tablets, USP 500 mg and 1000 mg**

**January 16, 2024**

Dear Customer,

This notice is to inform you of a product recall involving:

<b>Product Name</b>	<b>Package Description</b>	<b>Lot Number</b>	<b>NDC Number</b>	<b>Expiration Date</b>
Niacin Extended-Release Tablets, USP 500 mg	90 count	DNE0771A	47335-539-81	06/2025
Niacin Extended-Release Tablets, USP 500 mg	90 count	DNE0857A	47335-539-81	07/2025
Niacin Extended-Release Tablets, USP 500 mg	90 count	DNE0959A	47335-539-81	07/2025
Niacin Extended-Release Tablets, USP 1000 mg	90 count	DNE0788A	47335-613-81	07/2025

See enclosed product labeling.

This recall has been initiated in response to microbial contamination in stagnant water found in the duct of the manufacturing equipment.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on November 1, 2023.

Immediately examine your inventory and quarantine product subject to 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 notification 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, contact Inmar, Inc. at [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-877-815-1893 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.

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

*Christopher Leonor*

*01/16/2024*

Christopher Leonor

Sun Pharmaceutical Industries, Inc.

Associate Director, North America Supply Chain Quality & FDA Liaison


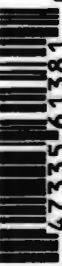


Enclosure:

Niacin Extended-Release Tablets, USP 500 mg: Bottle Labeling

<p>Each film-coated tablet contains 500 mg of niacin USP.</p> <p><b>USUAL DOSAGE:</b> See attached package insert for complete directions for use.</p> <p>Do not accept if seal over bottle opening is broken or missing.</p> <p>Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].</p> <p>Dispense in tight container with child-resistant closure.</p> <p>Patient information available at <a href="https://www.sunpharma.com/usa/products">https://www.sunpharma.com/usa/products</a></p>	<p>NDC 47335-539-01</p> <p><b>Niacin Extended-Release Tablets, USP</b></p> <p><b>500 mg</b></p> <p><b>PHARMACIST: Dispense with Patient Information to each patient.</b></p> <p>Rx only 90 Tablets</p> 	 <p>4733553981</p>	<p>Distributed by: Sun Pharmaceutical Industries, Inc. Crainbury, NJ 08512</p> <p>Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dabra-396 191, (U.T. of D &amp; NH), India.</p> <p>5237328      DNH/DRUGS/NH/138</p>
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Niacin Extended-Release Tablets, USP 1000 mg: Bottle Labeling

<p>Each film-coated tablet contains 1000 mg of niacin USP.</p> <p><b>USUAL DOSAGE:</b> See attached package insert for complete directions for use.</p> <p>Do not accept if seal over bottle opening is broken or missing.</p> <p>Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].</p> <p>Dispense in tight container with child-resistant closure.</p> <p>Patient information available at <a href="https://www.sunpharma.com/usa/products">https://www.sunpharma.com/usa/products</a></p>	<p>NDC 47335-613-01</p> <p><b>Niacin Extended-Release Tablets, USP</b></p> <p><b>1000 mg</b></p> <p><b>PHARMACIST: Dispense with Patient Information to each patient.</b></p> <p>Rx only 90 Tablets</p> 	<p>Distributed by: Sun Pharmaceutical Industries, Inc. Crainbury, NJ 08512</p> <p>Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dabra-396 191, (U.T. of D &amp; NH), India.</p> <p>DNH/DRUGS/NH/138</p> <p>5237331</p>	 <p>47335613810</p>
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For return of affected product, please email [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-877-815-1893.



## **URGENT: DRUG RECALL – RESPONSE FORM**

**Please Complete This Form and Fax to: 817-868-5362**

**or Email to: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)**

**Please check ALL appropriate boxes.**

- I have read and understand the recall instructions provided in the January 16, 2024 letter.
- I have checked our stock and have quarantined inventory consisting of \_\_\_\_\_ units (number of full cartons) or \_\_\_\_\_ prescription packs (partial cartons).

Indicate disposition of recalled product:

- returned (**specify quantity, date and method**)/held for return;

Number of Labels Required for Return to Inmar: \_\_\_\_\_

- previously destroyed (**specify quantity, date and method**);

I have identified and notified my retail customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or

- Attached is a list of retail customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product?  Yes  No

If yes, please explain: \_\_\_\_\_

For return of affected product, please email [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-877-815-1893.



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<b>Product Name</b>	<b>Package Description</b>	<b>Lot Number</b>	<b>NDC Number</b>	<b>Expiration Date</b>	<b>Total Number of Units (number of full cartons) or prescription packs (partial cartons)</b>
Niacin Extended-Release Tablets, USP 500 mg	90 count	DNE0771A	47335-539-81	06/2025	
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Niacin Extended-Release Tablets, USP 1000 mg	90 count	DNE0788A	47335-613-81	07/2025	

Please check the appropriate box(es) to describe your business

- |   |  |
|---|--|
| <input type="checkbox"/> wholesaler/distributor         | <input type="checkbox"/> retailer                  |
| <input type="checkbox"/> grocery corporate headquarters | <input type="checkbox"/> hospital pharmacies       |
| <input type="checkbox"/> repacker                       | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> pharmacy                       | <input type="checkbox"/> Other:                    |

Customer Name: \_\_\_\_\_ Title: \_\_\_\_\_

Company: \_\_\_\_\_ DEA Number: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Phone Number: \_\_\_\_\_



## **URGENT: DRUG RECALL - RESPONSE FORM**

Customer Email Address: \_\_\_\_\_

Customer Debit Memo Number: \_\_\_\_\_

Wholesaler: \_\_\_\_\_ City\State: \_\_\_\_\_

Wholesaler DEA Number: \_\_\_\_\_

Event ID: RCL005-2024 / N131127