



## **URGENT: DRUG RECALL**

### **Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg**

**July 9, 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>
Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg	100 count	231067	57664-233-88	04/2025
Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg	100 count	231069	57664-233-88	04/2025

See enclosed product labeling.

This recall has been initiated based on failing dissolution results for Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg, Batches 231067 and 231069 discovered through FDA sampling and analysis.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on June 14, 2023.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your retailer customers and notify them at once of this product recall. Your notification to your retailer 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 1-877-891-4123 Monday to Friday from 9:00 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.

A handwritten signature in cursive script that reads "Christopher Leonor".

07/09/2024

Christopher Leonor

Sun Pharmaceutical Industries, Inc.

Associate Director, North America Supply Chain Quality & FDA Liaison



Enclosures:  
Nitrofurantoin Capsules, USP (Macrocrystals): Bottle Label

**NDC 57664-233-88**  
**Nitrofurantoin Capsules, USP (Macrocrystals)**  
**100 mg**

**Rx Only**  
**100 Capsules**

**SUN PHARMA**

Each capsule contains:  
Nitrofurantoin, USP ..... 100 mg (macrocrystals)

**Usual Dosage:** See package insert for complete product information.

**Pharmacist Information:** Dispense in a tight, light-resistant container with child resistant closure as defined in USP.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Protect from light and moisture.


**Keep this and all drugs out of the reach of children.**

**Manufactured by:** Sidmak Laboratories (India) Pvt. Ltd. Plot No. 20, Pharmacy, Selaqui Industrial Area, Dehradun - 248 197 Uttarakhand, India

**Distributed by:**  
**Sun Pharmaceutical Industries, Inc.**  
Cranbury, NJ 08512  
6635L03

Rev. 09/18

M.L.No. 38/UA/2007  
P2061025  
4270237/PLJ01



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**UVZ**



Nitrofurantoin Capsules, USP (Macrocrystals): Shipper Label

**Pharmacist Information:**

Dispense in a tight, light resistant container with child resistant closure as defined in USP

Keep this and all drugs out of the reach of children

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from light and moisture.

Each capsule contains:  
Nitrofurantoin, USP.....100mg  
(macrocrystals)

6635L02  
08/14

NDC 57664-233-88

**Nitrofurantoin  
Capsules, USP  
(Macrocrystals)**

**100mg**

Rx Only  
Case Quantity: 288  
Bottle: 100 Capsules



**Usual Dosages**

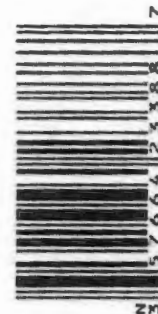
See package insert for complete product information

**Manufactured by:**

Sidmak Laboratories (India) Pvt. Ltd.  
Plot No. 20, Pharmacy Selaqui  
Industrial Area Dehradun 248 197  
Uttarakhand, India

**Distributed by:**

Sun Pharmaceutical  
Industries Inc  
270 Prospect Plains  
Cranbury, NJ 08512



M. L. No. 38/UA/2007  
P2061140 4270237/SL/00

Lot No

Exp.

For return of affected product, please email [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-877-891-4123.

**Sun Pharmaceuticals Industries, Inc.**  
**URGENT: DRUG RECALL – RESPONSE FORM**  
**Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg**  
**Retail Level**  
**07/09/2024**



**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#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>	

**Address:**

City:	State:	Zip:
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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	Total Number of Units (number of full cartons) or prescription packs (partial cartons)
Nitrofurantoin Capsules, USP (Macrocrystals) 100 mg	100 count	57664-233-88	231067	04/2025	
		57664-233-88	231069	04/2025	

If you have any questions regarding this form or product return please contact Inmar at (1-877-891-4123)

Office hours 9:00 am to 5:00pm EST Monday through Friday.

Please fax this form to: 1-817-868-5362 or E-mail [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)

**RCL194-24 / N131198**