URGENT: DRUG RECALL - REVISED

Morphine Sulfate Extended-Release Tablets, 100 mg CII

February 25, 2025

Dear Customer,

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

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Morphine Sulfate Extended-Release Tablets, 100 mg CII	100 count bottle	AD16615	63304-452-01	07/2025

See enclosed product labeling.

This recall has been initiated in response to Out of Specification (OOS) results observed in dissolution test for Morphine Sulfate Extended-Release Tablets, 100 mg, Batch AD16615, during analysis at 12 month long term stability station (25°C, 60%RH).

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on October 12, 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 or call 1-877-560-2582 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.

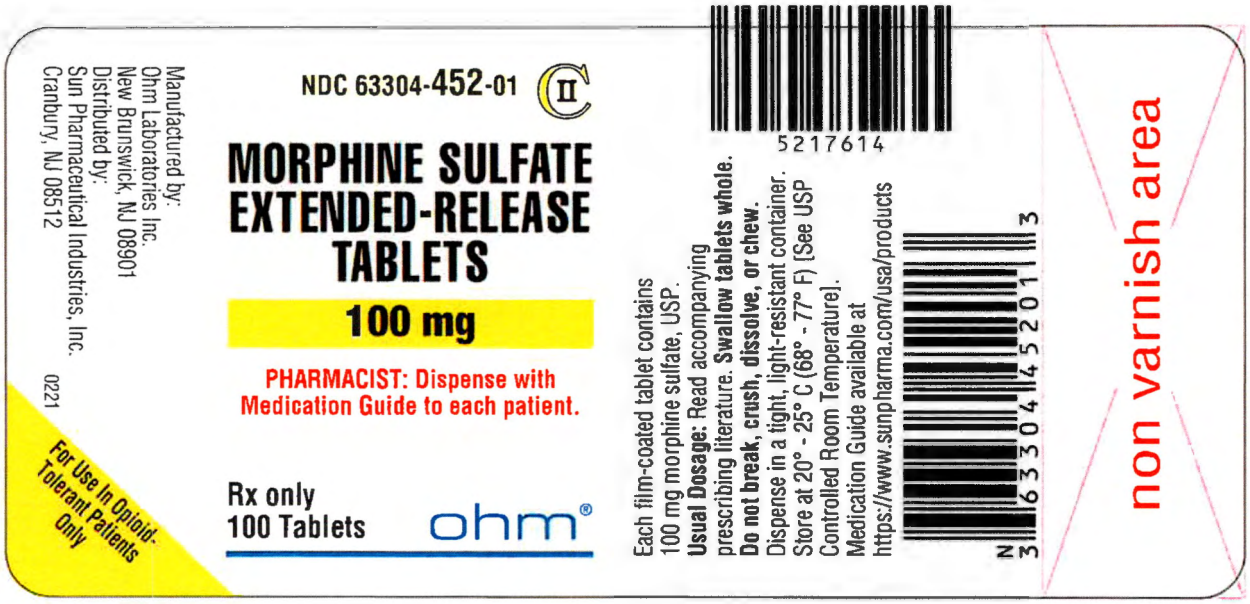
This recall is being made with the knowledge of the Food and Drug Administration.

02/25/2025

Christopher Leonor
Sun Pharmaceutical Industries, Inc.
Associate Director, North America CMO & Supply Chain Quality Head

For return of affected product, please email rxrecalls@inmar.com or call 1-877-560-2582.

Enclosure:
Morphine Sulfate Extended-Release Tablets, 100 mg CII: Label



For return of affected product, please email rxrecalls@inmar.com or call 1-877-560-2582.

Sun Pharmaceuticals Industries, Inc.

URGENT: DRUG RECALL – RESPONSE FORM - REVISED

Morphine Sulfate Extended-Release Tablets, 100 mg, 100 count

Retail Level - CII

2/25/2025

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	Total Number of Units (number of full cartons) or prescription packs (partial cartons)
Morphine Sulfate Extended-Release Tablets, 100 mg CII	100 count bottle	63304-452-01	AD16615	07/2025	

If you have any questions regarding this form or product return please contact Inmar at (1-877-560-2582)

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

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

RCL003-25 / N131256