

URGENT: DRUG RECALL

Doxycycline Capsules, USP, 75 mg and 100 mg

March 11, 2020

Dear Customer,

This recall has been initiated in response to an identified variance to our established process which represents that these lots were not manufactured under Current Good Manufacturing Practices (CGMP). Although the affected drug product meets all testing specifications, recalls due to non-compliance with CGMP reflect manufacturing processes that are not adequately controlled by a firm.

CGMP deviations or violations may result in the inability to assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess and may lead to products of unacceptable quality. While specific risks to patients, from use of these adulterated products, cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products.

This product recall is for the products identified in the table.

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Doxycycline Capsules, USP, 100 mg	50 Count	3983720	63304-616-50	10/2020
Doxycycline Capsules, USP, 100 mg	50 Count	3990461	63304-616-50	11/2020
Doxycycline Capsules, USP, 100 mg	50 Count	3990464	63304-616-50	11/2020
Doxycycline Capsules, USP, 100 mg	50 Count	3990465	63304-616-50	11/2020
Doxycycline Capsules, USP, 100 mg	50 Count	3990466	63304-616-50	11/2020
Doxycycline Capsules, USP, 100 mg	50 Count	3990470	63304-616-50	11/2020
Doxycycline Capsules, USP, 75 mg	100 Count	AA39490	63304-615-01	03/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA42499	63304-616-50	04/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA42510	63304-616-50	04/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA44468	63304-616-50	04/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA44470	63304-616-50	04/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA55073	63304-616-50	05/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA55074	63304-616-50	05/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA55075	63304-616-50	05/2021
Doxycycline Capsules, USP, 100 mg	50 Count	AA61486	63304-616-50	06/2021

See enclosed product labeling for ease in identifying the product at the retail level.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on May 24, 2019.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed this product, please identify your wholesale and retail customers and notify them at once of this product recall. Your notification to your wholesale and 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, Inc.
3845 Grand Lakes Way
Suite 125
Grand Prairie, TX 75050

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-800-967-5952, 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 U.S. Food and Drug Administration.

Aimee Albanese 03-11-2020

Aimee Albanese
Sun Pharmaceutical Industries, Inc.
Associate Director, Cluster Quality Support

Enclosure

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

Enclosures:
 Doxycycline Capsules, 75 mg (100 Count Bottle) Labeling

Manufactured by:
 Ohm Laboratories, Inc.
 New Brunswick, NJ 08901
 Distributed by:
 Sun Pharmaceutical Industries, Inc.
 Cranbury, NJ 08512

NDC 63304-615-01

**DOXYCYCLINE
 CAPSULES, USP**

75 mg

Rx only
 100 Capsules

ohm®

0817

FPO
 0000000

3 163304 61501 2

non varnish area

EACH CAPSULE CONTAINS:
 Doxycycline monohydrate, USP
 equivalent to 75 mg of doxycycline.
USUAL DOSAGE: See a accompanying
 prescribing information.
 Dispense in a tight, light-resistant
 container as defined in the USP/NF.
 Store at 20° - 25° C (68° - 77° F) [See
 USP Controlled Room Temperature].
 Protect from light.

Doxycycline Capsules, 100 mg (50 Count) Labeling

Manufactured by:
 Ohm Laboratories, Inc.
 New Brunswick, NJ 08901
 Distributed by:
 Sun Pharmaceutical Industries, Inc.
 Cranbury, NJ 08512

NDC 63304-616-50

**DOXYCYCLINE
 CAPSULES, USP**

100 mg

Rx only
 50 Capsules

ohm®

0817

FPO
 0000000

3 163304 61650 7

non varnish area

EACH CAPSULE CONTAINS:
 Doxycycline monohydrate, USP
 equivalent to 100 mg of doxycycline.
USUAL DOSAGE: See a accompanying
 prescribing information.
 Dispense in a tight, light-resistant
 container as defined in the USP/NF.
 Store at 20° - 25° C (68° - 77° F) [See
 USP Controlled Room Temperature].
 Protect from light.

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.

URGENT: DRUG RECALL – RESPONSE FORM

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

or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number
Doxycycline Capsules, USP, 100 mg	50 Count	3983720, 3990461, 3990464, 3990465, 3990466, 3990470, AA42499, AA42510, AA44468, AA44470, AA55073, AA55074, AA55075, AA61486	63304-616-50
Doxycycline Capsules, USP, 75 mg	100 Count	AA39490	63304-615-01

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the March 11, 2020 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 or call 1-800-967-5952.

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Doxycycline Capsules, USP, 75 mg	100 Count	AA39490	63304-615-01

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

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

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.