Glenmark
A new way for a new world

RECALL RETURN RESPONSE FORM
Pravastatin Sodium Tablets, USP 80 mg container pack (Tablets)
(Bottle pack 90's and 500's)
NDC for 90's Count (68462-198-90) and NDC for 500's (68462-198-05)

Wholesaler Level
06/28/2024

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal 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 Glenmark Pharmaceuticals Inc.:

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 wholesale 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_____.

Sr. No.	Item Description	NDC	Batch Number	Pack style (Container)	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
1	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211249	90's	Jun-24	
2	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211264	90's	Jun-24	

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Sr. No.	Item Description	NDC	Batch Number	Pack style (Container)	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
3	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211266	90's	Jun-24	
4	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211286	90's	Jun-24	
5	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211525	90's	Jul-24	
6	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211535	90's	Jul-24	
7	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211549	90's	Jul-24	
8	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211787	90's	Aug-24	
9	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17211801	90's	Aug-24	
10	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17212041	90's	Sep-24	
11	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17212088	90's	Oct-24	
12	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17212106	90's	Oct-24	
13	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17212346	90's	Nov-24	
14	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17212345	90's	Nov-24	
15	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17220053	90's	Dec-24	
16	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17220054	90's	Dec-24	
17	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17220055	90's	Dec-24	
18	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17220309	90's	Jan-25	
19	Pravastatin Sodium Tablets, USP 80 mg	68462-198-90	17220310	90's	Jan-25	
20	Pravastatin Sodium Tablets, USP 80 mg	68462-198-05	17211290	500's	Jun-24	

If you have any questions regarding this form or product return please contact Inmar at 877-887-2930 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com
Recall Event ID: N131184 / RCL172-2024

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URGENT: DRUG RECALL

Pravastatin Sodium Tablets, USP 80 mg container pack (Tablets)

(Bottle pack 90's and 500's)

NDC for 90's Count (68462-198-90) and NDC for 500's (68462-198-05)

June 28, 2024

Dear Customer,

This is to inform you of a voluntary recall to the Wholesale level involving the following:
Pravastatin Sodium Tablets, USP 80 mg

Sr. No.	NDC	Product Name	Batch Number	Expiry Date
1	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211249	Jun-24
2	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211264	Jun-24
3	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211266	Jun-24
4	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211286	Jun-24
5	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211525	Jul-24
6	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211535	Jul-24
7	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211549	Jul-24
8	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211787	Aug-24
9	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17211801	Aug-24
10	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17212041	Sep-24
11	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17212088	Oct-24
12	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17212106	Oct-24
13	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17212346	Nov-24
14	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17212345	Nov-24
15	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17220053	Dec-24
16	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17220054	Dec-24
17	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17220055	Dec-24
18	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17220309	Jan-25
19	68462-198-90	PRAVASTATIN SODIUM TABLETS, USP 80MG 90'S	17220310	Jan-25
20	68462-198-05	PRAVASTATIN SODIUM TABLETS, USP 80MG 500'S	17211290	Jun-24

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Recall of these batches have been initiated as an abundance of caution against the Out of Specification results for the test of dissolution (By UV) for the batches 17210413 & 17210903, reported at shelf life time point in the long term stability (commercial batches). Batches 17210413 & 17210903 are not part of recall as these have been expired.

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product. Glenmark Pharmaceuticals Inc. initiated shipment of this product (from 20 batches) from July 26, 2021.

Examine your inventory and if you have any inventory available pertains to batch specified in above table then quarantine it immediately.

We are requesting the batch specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Recall Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return please contact Inmar at 877-887-2930

Inmar office hours are Monday through Friday, from 9am to 5pm EST.

Lastly, this recall is being made with the knowledge of the Food and Drug Administration.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Digitally signed by Thomas Callaghan
Date: 2024.06.28 08:44:25 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall Return Response Form

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa