glenmark
A new way for a new world

URGENT: DRUG RECALL

Diltiazem Hydrochloride Extended Release Capsules 60 mg, 90 mg and 120 mg

(100's Bottles pack Container)

NDC: 68462-850-01 (60 mg), 68462-851-01 (90 mg) & 68462-562-01 (120 mg)

(Glenmark)

November 1, 2024

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you of that Glenmark is initiating a voluntary recall to the Retail level involving the following prescription product:

Diltiazem Hydrochloride Extended Release Capsules 60 mg, 90 mg & 120 mg (100's Pack Container)

S. No.	NDC	Batch #	Pack Size	Expiry
1.	68462-851-01	17222452	100 capsules	11/2024
2.	68462-562-01	17222470	100 capsules	11/2024
3.	68462-850-01	17222544	100 capsules	11/2024
4.	68462-562-01	17222547	100 capsules	11/2024
5.	68462-562-01	17230304	100 capsules	12/2024
6.	68462-562-01	17230598	100 capsules	02/2025
7.	68462-851-01	17230607	100 capsules	02/2025
8.	68462-562-01	17230680	100 capsules	11/2024
9.	68462-850-01	17230784	100 capsules	03/2025
10.	68462-850-01	17231080	100 capsules	04/2025

The recall to the ***retail level*** of the above identified product batches for Diltiazem Hydrochloride Extended Release Capsules has been initiated by Glenmark out of an abundance of precaution because the results of certain finished product analysis does not comply with the Agency's current recommended limit of "N-Nitroso-Desmethyl-Diltiazem" i.e. 0.074 ppm.

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

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on 27 Jan. 2023.

In addition, if you are a wholesaler/ distributor, who has further distributed this product, please identify those 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. Again, this recall should be carried out to the retail level only. Because this is not a consumer level recall, notice to the consumer level is not required.

We are requesting the batches 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 866-945-0822

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

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

Thank you for your cooperation,

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

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan Thomas Callaghan Digitally signed by Thomas Callaghan Date: 2024.11.01 10:48:15 -04'00'

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

Glenmark
A new way for a new world

Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

DILTIAZEM HYDROCHLORIDE EXTENDED RELEASE CAPSULES 60 MG, 90 MG & 120 MG (100's PACK CONTAINER)

(NDC: 68462-850-01 (60 mg), 68462-851-01 (90 mg) & 68462-562-01 (120 mg))

Retail Level

11/01/2024

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 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_____.

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Diltiazem Hydrochloride Extended Release Capsules, USP 90 mg	68462-851-01	17222452/100 capsules	11/2024	
Diltiazem Hydrochloride Extended Release Capsules, USP 120 mg	68462-562-01	17222470/100 capsules	11/2024	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Diltiazem Hydrochloride Extended Release Capsules, USP 60 mg	68462-850-01	17222544/100 capsules	11/2024	
Diltiazem Hydrochloride Extended Release Capsules, USP 120 mg	68462-562-01	17222547/100 capsules	11/2024	
Diltiazem Hydrochloride Extended Release Capsules, USP 120 mg	68462-562-01	17230304/100 capsules	12/2024	
Diltiazem Hydrochloride Extended Release Capsules, USP 120 mg	68462-562-01	17230598/100 capsules	02/2025	
Diltiazem Hydrochloride Extended Release Capsules, USP 90 mg	68462-851-01	17230607/100 capsules	02/2025	
Diltiazem Hydrochloride Extended Release Capsules, USP 120 mg	68462-562-01	17230680/100 capsules	11/2024	
Diltiazem Hydrochloride Extended Release Capsules, USP 60 mg	68462-850-01	17230784/100 capsules	03/2025	
Diltiazem Hydrochloride Extended Release Capsules, USP 60 mg	68462-850-01	17231080/100 capsules	04/2025	

If you have any questions regarding this form or product return please contact Inmar at 866-945-0822 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 RCL263-24 / N131231