

URGENT: DRUG RECALL

Carvedilol tablets, USP 25mg NDC: 68462-165-05 (500's Bottles pack Container)

Carvedilol tablets, USP 12.5mg NDC: 68462-164-05 (500's Bottles pack Container)

August 5, 2025

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:

For Carvedilol tablets, USP 25 mg **500 bottle pack**

S. No.	NDC	Batch #	Pack Size	Expiry
1.	68462-165-05	17241213	500 bottle pack	06/2026
2.	68462-165-05	17241215	500 bottle pack	06/2026
3.	68462-165-05	17241224	500 bottle pack	06/2026

For Carvedilol tablets, USP 12.5 mg **500 bottle pack**

Sr. No.	NDC Number	Batch	Pack size	Exp. Date
1.	68462-164-05	17241257	500 bottle pack	06/2026
2.	68462-164-05	17241258	500 bottle pack	06/2026
3.	68462-164-05	17241279	500 bottle pack	06/2026

Recall of these Carvedilol tablets drug product batches have been initiated out of an abundance of precaution due to finished product analysis results confirm that aforementioned batches do not

comply with the Agency's recommended limit of N-Nitroso Carvedilol Impurity-1 (NNCI) i.e. NMT 4.0 PPM.

The Health hazard assessment concluded that Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time, but there is no immediate risk to patients taking the medication, and the probability of serious adverse health consequences is remote. Based upon the overall assessment, it is concluded that there is no clinically significant risk of health hazard due to consumption of the above-mentioned batches of Carvedilol Tablets USP.

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 10/24/2024.

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 (877) 296-1629

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.

Thank you for your cooperation,

thomas.callaghan@gle
nmarkpharma.com

Digitally signed by
thomas.callaghan@glenmarkpharma.com
Date: 2025.08.05 14:09:56 -04'00'

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Recall Return Response Form

Product Labels

Rx Only

500 Tablets


NDC 68462-164-05

Carvedilol Tablets, USP

12.5 mg

glenmark

Each tablet contains carvedilol USP, 12.5 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Manufactured by:
Glenmark Pharmaceuticals Ltd.
Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur,
Dist.-Dhar, Madhya Pradesh 454 775, India
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19
25/9/2010



Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE522420919-1

Rx Only

500 Tablets


NDC 68462-165-05

Carvedilol Tablets, USP

25 mg

glenmark

Each tablet contains carvedilol USP, 25 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Manufactured by: **Glenmark Pharmaceuticals Ltd.**
Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur,
Dist.-Dhar, Madhya Pradesh 454 775, India
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19
25/9/2010



Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE522440919-1

UNFINISHED AREA

Eglenmark

12.5 mg


Each tablet contains carvedilol USP, 12.5 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Manufactured by:
Glenmark Pharmaceuticals Ltd.
Plot No. 2, Phase-2, Parkma Zone SEZ, Pithampur,
Dist.-Dhar, Madhya Pradesh 454 775, India
Manufactured for:
**Glenmark
Pharmaceuticals
Inc., USA**
Mahwah, NJ 07430
09/19
25/9/2010
PES2242019-1

Questions ? 1 (888) 721-7115
www.glenmark-pharma-usa.com

PE522420919-1

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

G GLENMARK PHARMACEUTICALS LTD.

<div><div></div><div><div>GLENMARK PHARMACEUTICALS LTD.</div></div></div>		DATE:		PANTONE SHADE NO. <div><div><div></div><div>BLACK</div></div><div><div></div><div>143 C</div></div><div><div></div><div>186 C</div></div></div>	
PRODUCT NAME: Carvedilol tablets USP 12.5 mg		PKG. DEV.:		Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PEE2242 VERSION: 0919-1					
PHARMACODE:		RA		Regulatory Text	
COUNTRY: USA		QA:		Enter Text	
LOCATION: INDORE		PRODUCTION:		Machine Seriality	
PACK: LABEL - 500 TABLETS					
ACTUAL SIZE: 130 mm x 50 mm		REMARKS:			
SPECIFICATION: A LUV VARNISH COATED FASPRINT NG/PERMANENT (HITAC) PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED					

DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED

DATE: PANTONE SHADE NO: BLACK 364 C 186 C		PKG. DEV.: Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout		RA Regulatory Text		QA: Entire Text		PRODUCTION: Machine Suitability		REMARKS:	
PRODUCT NAME: Carvedilol Tablets USP 25 mg		ITEM CODE: PE52244		PHARMACODE:		COUNTRY: USA		LOCATION: INDORE		PACK : LABEL - 500 TABLETS	
ACTUAL SIZE: 130 mm x 55 mm		SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK, BATCH PRINTING AREA REMAINS UNVARNISHED									

Rx Only

500 Tablets

**Carvedilol
Tablets, USP**

NDC 68462-165-05

glenmark®

Each tablet contains carvedilol USP, 25 mg.
Product meets USP Dissolution Test 2.
Usual Dosage: See accompanying prescribing information.
Store at 2°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

Manufactured by: Glenmark Pharmaceuticals Ltd., Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh-454 775, India

Manufactured for:
**Glenmark
Pharmaceuticals
Inc., USA**
Mahwah, NJ 07430
09/19
25/9/2010
PES224A093-1

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

JAR SIZE : 250 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 55 mm

UNWRAPPED AREA
32 mm x 55 mm

Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

Carvedilol tablets, USP 25mg NDC: 68462-165-05 (500's Bottles pack Container)

Carvedilol tablets, USP 12.5mg NDC: 68462-164-05 (500's Bottles pack Container)

Retailer Level

8/5/2025

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#:
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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:
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Contact Signature:	Date:
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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
Carvedilol tablets, USP 25 mg	68462-165-05	17241213/500`s	06/2026	
Carvedilol tablets, USP 25 mg	68462-165-05	17241215/500`s	06/2026	
Carvedilol tablets, USP 25 mg	68462-165-05	17241224/500`s	06/2026	
Carvedilol tablets, USP 12.5mg	68462-164-05	17241257/500`s	06/2026	
Carvedilol tablets, USP 12.5mg	68462-164-05	17241258/500`s	06/2026	
Carvedilol tablets, USP 12.5mg	68462-164-05	17241279/500`s	06/2026	

If you have any questions regarding this form or product return please contact Inmar at (877) 296-1629

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 N131336 / RCL177-25

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