

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

Glenmark
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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

Page 2 of 4



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 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 ablets, Carvedilol NDC 68462-165-05 **Glenmark 500 Tablets** Each tablet contains carvedilol USP, 25 mg. Product meets USP Dissolution Test 2 Usual Dosage: See accompanying prescribing 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

Rx Only fablets, USP Carvedilol NDC 68462-164-05 12.5 Glenmank **500 Tablets** mg

Each tablet contains carvedlol USP, 12.5 mg. Product meets USP Dissolution Test 2 Usual Dosave: 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 PE522420919-1



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



JAH SIZE: 150 CC SAME SIZE ARTWORK LABEL SIZE: 130 mm x 50 mm

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: Manufactured Dist.-Dhar, Madhya Pradesh 454 775, India Manufactured for: 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 Manwah, NJ 07430

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

09/19 25/9/2010

PE522420919-1

MINIMUM FONT SIZE: 5.1 PT

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 COUNTRY: __ ACTUAL SIZE: PRODUCT NAME: Carvedilol Tablets USP 12.5 mg PHARMACODE: . ITEM CODE: PE52242 GLENMARK PHARMAGEUTICALS LTD. INDORE LABEL - 500 TABLETS USA 130 mm x 50 mm VERSION: 0919-1 DATE: REMARKS: PRODUCTION: 2 RA PKG. DEV .: Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout Entire Text PANTONE SHADE NO: BLACK 186 C 143 C

INVARNISHED AREA 35 mm x 50 mm

SPECIFICATION: 40 GSM Bible Paper Folded gluing 34x35mm perl PACK: LOCATION: Goalindore COUNTRY: US my Ampailing ASI. TTEM CODE: PE64943 AEHRION: 0853-1 PKG. DEV.: PRODUCT NAME: LT CARVEDLOLS 126 25-12-52 USSPIRAL S GLEMMARK PHARMACEUTICALS LTD. DATES OR 2023

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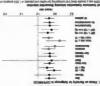
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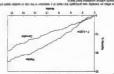
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General information about Car Trablets

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		BEMARKS:	ACTUAL SIZE: 130 mm x 55 mm
			PACK: LABEL - 500 TABLETS
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	Entire Text	:AQ	COUNTRY: USA
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int area, Pack	Item code, Versio of Design, overpri	PKG. DEV.:	PRODUCT NAME: Carvedilol Tablets USP 25 mg
NOE NO: 186 C 364 C	HS 3NOTNA9	:3TAO	GLENMARK PHARMACEUTICALS LTD.

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

<u>Please fill out this form completely.</u> 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, it	f it is not provided, the proc	essing of your form	will be delayed.
Address:			
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as soon as possible. Upon receipt of this Respon	nse Form, Inmar, will issu	ue return authoriza	ation label(s) Pleas
indicate the # of needed hox 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