

**MARKET WITHDRAWAL RETURN RESPONSE FORM**  
**DRUG MARKET WITHDRAWAL**  
**CARVEDILOL TABLETS USP 12.5 MG and 25 MG**  
**(100's & 500's TABLETS CONTAINER)**  
**(NDC 68462-164-01, 68462-165-01, 68462-164-05 and 68462-165-05)**  
**Retail Level**  
**7/31/2025**

**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#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>		
Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:		Date:
DEBIT MEMO# (If unsure, leave blank):		

**Retailer 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 withdrawal items. **OR**

☐ I have quarantined and listed in the box below the quantity of withdrawal 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 \_\_\_\_\_.

**Carvedilol Tablets USP 12.5 mg**

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240200/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240207/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240213/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240219/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240238/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240243/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240245/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240248/500`s	Jan-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240460/500`s	Feb-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240467/500`s	Feb-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240468/500`s	Feb-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240469/500`s	Feb-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240860/500`s	Apr-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240861/500`s	Apr-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240868/500`s	Apr-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17240870/500`s	Apr-26	
Carvedilol Tablets USP 12.5 mg	68462-164-01	17240871/100`s	Apr-26	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Carvedilol Tablets USP 12.5 mg	68462-164-05	17241280/500's	Jul-26	
Carvedilol Tablets USP 12.5 mg	68462-164-05	17241298/500's	Jul-26	

**Carvedilol Tablets USP 25 mg**

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Carvedilol Tablets USP 25 mg	68462-165-05	17231805/500's	Jul-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231879/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231891/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231897/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231905/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231928/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231935/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17231944/500's	Aug-25	
Carvedilol Tablets USP 25 mg	68462-165-05	17240452/500's	Feb-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240511/500's	Feb-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240513/500's	Feb-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240514/500's	Feb-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240666/500's	Mar-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240687/500's	Mar-26	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
Carvedilol Tablets USP 25 mg	68462-165-05	17240698/500's	Mar-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240704/500's	Mar-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240705/500's	Mar-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240746/500's	Apr-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240758/500's	Apr-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240908/500's	May-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240915/500's	May-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240922/500's	May-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240934/500's	May-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17240941/500's	May-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241232/500's	Jun-26	
Carvedilol Tablets USP 25 mg	68462-165-01	17241239/100's	Jun-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241854/500's	Oct-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241855/500's	Oct-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241913/500's	Oct-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241914/500's	Oct-26	
Carvedilol Tablets USP 25 mg	68462-165-05	17241928/500's	Oct-26	



If you have any questions regarding this form or product return please contact Inmar at (877) 296-1460

Office hours 9am to 5pm EST Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)**

**Market withdrawal Event ID N131337 / RCL176-25**

**Market withdrawal Event ID N131337 / RCL176-25**

**DRUG MARKET WITHDRAWAL**  
**CARVEDILOL TABLETS USP 12.5 MG and 25 MG**  
**(100's & 500's TABLETS CONTAINER)**  
**(NDC 68462-164-01, 68462-165-01, 68462-164-05 and 68462-165-05)**  
**(Glenmark)**

July 31, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a Market Withdrawal to the Retail level involving the following prescription product:

**Carvedilol Tablets USP 12.5 mg:**

<b>Sr. No.</b>	<b>Product name with Strength</b>	<b>NDC Code</b>	<b>Batch</b>	<b>Pack Size</b>	<b>Expiry Date</b>
1.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240200	500's Tablets Pack	Jan-26
2.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240207	500's Tablets Pack	Jan-26
3.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240213	500's Tablets Pack	Jan-26
4.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240219	500's Tablets Pack	Jan-26
5.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240238	500's Tablets Pack	Jan-26
6.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240243	500's Tablets Pack	Jan-26
7.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240245	500's Tablets Pack	Jan-26
8.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240248	500's Tablets Pack	Jan-26
9.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240460	500's Tablets Pack	Feb-26
10.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240467	500's Tablets Pack	Feb-26
11.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240468	500's Tablets Pack	Feb-26
12.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240469	500's Tablets Pack	Feb-26
13.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240860	500's Tablets Pack	Apr-26
14.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240861	500's Tablets Pack	Apr-26
15.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240868	500's Tablets Pack	Apr-26
16.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17240870	500's Tablets Pack	Apr-26
17.	Carvedilol Tablets USP 12.5 mg	68462-164-01	17240871	100's Tablets Pack	Apr-26
18.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17241280	500's Tablets Pack	Jul-26
19.	Carvedilol Tablets USP 12.5 mg	68462-164-05	17241298	500's Tablets Pack	Jul-26

**Carvedilol Tablets USP 25 mg:**

<b>Sr. No.</b>	<b>Product name with Strength</b>	<b>NDC Code</b>	<b>Batch</b>	<b>Pack Size</b>	<b>Expiry Date</b>
1.	Carvedilol Tablets USP 25 mg	68462-165-05	17231805	500's Tablets Pack	Jul-25
2.	Carvedilol Tablets USP 25 mg	68462-165-05	17231879	500's Tablets Pack	Aug-25
3.	Carvedilol Tablets USP 25 mg	68462-165-05	17231891	500's Tablets Pack	Aug-25
4.	Carvedilol Tablets USP 25 mg	68462-165-05	17231897	500's Tablets Pack	Aug-25
5.	Carvedilol Tablets USP 25 mg	68462-165-05	17231905	500's Tablets Pack	Aug-25
6.	Carvedilol Tablets USP 25 mg	68462-165-05	17231928	500's Tablets Pack	Aug-25
7.	Carvedilol Tablets USP 25 mg	68462-165-05	17231935	500's Tablets Pack	Aug-25
8.	Carvedilol Tablets USP 25 mg	68462-165-05	17231944	500's Tablets Pack	Aug-25
9.	Carvedilol Tablets USP 25 mg	68462-165-05	17240452	500's Tablets Pack	Feb-26
10.	Carvedilol Tablets USP 25 mg	68462-165-05	17240511	500's Tablets Pack	Feb-26
11.	Carvedilol Tablets USP 25 mg	68462-165-05	17240513	500's Tablets Pack	Feb-26
12.	Carvedilol Tablets USP 25 mg	68462-165-05	17240514	500's Tablets Pack	Feb-26
13.	Carvedilol Tablets USP 25 mg	68462-165-05	17240666	500's Tablets Pack	Mar-26
14.	Carvedilol Tablets USP 25 mg	68462-165-05	17240687	500's Tablets Pack	Mar-26
15.	Carvedilol Tablets USP 25 mg	68462-165-05	17240698	500's Tablets Pack	Mar-26
16.	Carvedilol Tablets USP 25 mg	68462-165-05	17240704	500's Tablets Pack	Mar-26
17.	Carvedilol Tablets USP 25 mg	68462-165-05	17240705	500's Tablets Pack	Mar-26
18.	Carvedilol Tablets USP 25 mg	68462-165-05	17240746	500's Tablets Pack	Apr-26
19.	Carvedilol Tablets USP 25 mg	68462-165-05	17240758	500's Tablets Pack	Apr-26
20.	Carvedilol Tablets USP 25 mg	68462-165-05	17240908	500's Tablets Pack	May-26
21.	Carvedilol Tablets USP 25 mg	68462-165-05	17240915	500's Tablets Pack	May-26
22.	Carvedilol Tablets USP 25 mg	68462-165-05	17240922	500's Tablets Pack	May-26
23.	Carvedilol Tablets USP 25 mg	68462-165-05	17240934	500's Tablets Pack	May-26
24.	Carvedilol Tablets USP 25 mg	68462-165-05	17240941	500's Tablets Pack	May-26
25.	Carvedilol Tablets USP 25 mg	68462-165-05	17241232	500's Tablets Pack	Jun-26
26.	Carvedilol Tablets USP 25 mg	68462-165-01	17241239	100's Tablets Pack	Jun-26
27.	Carvedilol Tablets USP 25 mg	68462-165-05	17241854	500's Tablets Pack	Oct-26
28.	Carvedilol Tablets USP 25 mg	68462-165-05	17241855	500's Tablets Pack	Oct-26
29.	Carvedilol Tablets USP 25 mg	68462-165-05	17241913	500's Tablets Pack	Oct-26
30.	Carvedilol Tablets USP 25 mg	68462-165-05	17241914	500's Tablets Pack	Oct-26
31.	Carvedilol Tablets USP 25 mg	68462-165-05	17241928	500's Tablets Pack	Oct-26

Glenmark is initiating a market withdrawal at the ***Retail level*** for the above-identified batches of Carvedilol Tablets USP 12.5mg, and 25mg due to ‘N-Nitroso Carvedilol I’ impurity results were observed above FDA-recommended acceptable limit of NMT 4.0 ppm for five (5) batches at 9-month long-term (25°C/60% RH) stability interval. Glenmark is separately initiating a voluntary recall of these Six (6) batches of Carvedilol Tablets USP 12.5mg, and 25mg that are within shelf life, and the results of these six (6) batches were observed above 3.5 ppm (FDA-recommended acceptable limit is NMT 4.0 ppm) at 9-month stability interval.

As an abundance of caution, Glenmark is initiating market withdrawal of above mentioned 50 batches of Carvedilol Tablets USP 12.5mg and 25mg that are within shelf life and the results are complying with the FDA recommended acceptable limit of NMT 4.0 ppm.

Glenmark has implemented corrective actions to control the ‘N-Nitroso Carvedilol I’ Impurity in the drug product since March 2025. These corrective actions comprise a strategy to control the levels of Nitrosamine impurity, using excipients with low nitrite content in the formulation. The above batches subjected to market recall and withdrawal, were manufactured before the implementation of the control strategy (Formulation using low nitrite content excipients).

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 see details of product batches listed in the 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 03 November 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 Market Withdrawal. Your notification to your retail customers may be enhanced by including a copy of this market withdrawal notification letter. Again, this market withdrawal should be carried out to the retail level only. Because this is not a consumer level market withdrawal, 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 Market Withdrawal 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](mailto:Rxrecalls@Inmar.com).

If you have any questions regarding your market withdrawal return please contact Inmar at (877) 296-1460

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

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

Thank you for your cooperation,

Sincerely,

**GLENMARK PHARMACEUTICALS INC., USA**

**thomas.callaghan@glenmarkpharma.com**

Thomas Callaghan

Digitally signed by  
thomas.callaghan@glenmarkpharma.com  
Date: 2025.07.31 09:00:52 -04'00'

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Market Withdrawal Return Response Form

NDC 68462-164-01  
**Carvedilol  
Tablets, USP**  
**12.5 mg**  
glenmark  
**Rx Only 100 Tablets**

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



PE522490919-1

Questions? 1 (888) 721-7115  
[www.glenmarkpharma-us.com](http://www.glenmarkpharma-us.com)

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

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



PE522420919-1

Questions? 1 (888) 721-7115  
[www.glenmarkpharma-us.com](http://www.glenmarkpharma-us.com)

**Rx Only     100 Tablets**

**NDC 68462-165-01**

**Carvedilol  
Tablets, USP**

**25 mg**

**glenmark**

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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  
PE522430919-1

Questions? 1 (888) 721-7115  
[www.glenmarkpharma-us.com](http://www.glenmarkpharma-us.com)

**Rx Only     500 Tablets**

**NDC 68462-165-05**

**Carvedilol  
Tablets, USP**

**25 mg**

**glenmark**

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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  
PE522440919-1

Questions? 1 (888) 721-7115  
[www.glenmarkpharma-us.com](http://www.glenmarkpharma-us.com)