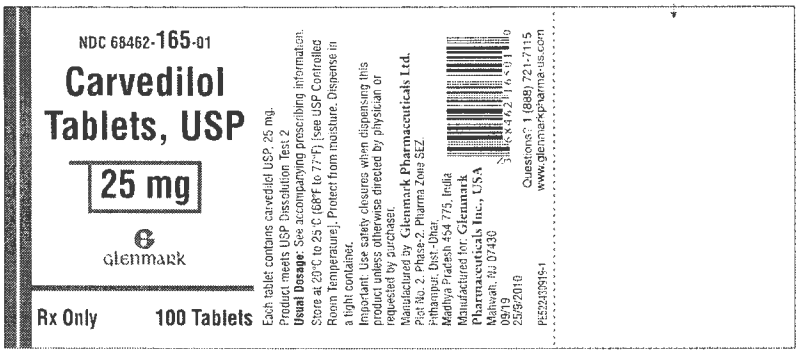
JAR SIZE : 60 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 45 mm



May Breedlove — Digitally signed by May Breedlove Date: 2019.11.06 10:14:51 -05'00'

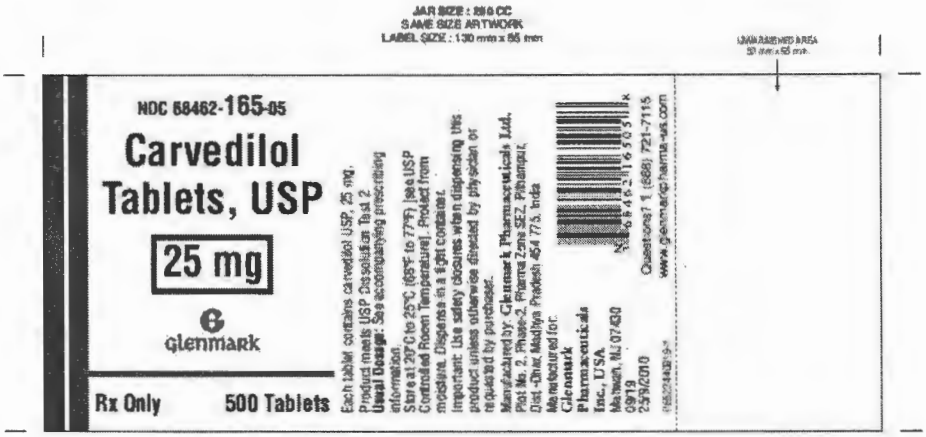
Donna-Marie Walters — Digitally signed by Donna-Marie Walters Date: 2019.11.06 10:45:06 -05'00'

Carole Capella — Digitally signed by Carole Capella Date: 2019.11.06 12:56:30 -05'00'

MINIMUM FONT SIZE: 4.5 PT

GLENMARK PHARMACEUTICALS LTD.		**DATE:**	**PANTONE SHADE NO:** BLACK 364 C 186 C
PRODUCT NAME: Carvedilol Tablets USP 25 mg		**PKG. OEV.:**	Item code Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE52243 **VERSION:** 0919-1		**RA**	Regulatory Text
PHARMACODE:		**QA:**	Entire Text
COUNTRY: USA		**PRODUCTION:**	Machine Suitability
LOCATION: INDORE		**REMARKS:**	
PACK : LABEL - 100 TABLETS			
ACTUAL SIZE: 105 mm x 45 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			

- 25 mg , 500's Count



May Breedlove
Digitally signed by May Breedlove
Date: 2019.11.06 10:14:15 -05'00'

Donna-Marie Walters
Digitally signed by Donna-Marie Walters
Date: 2019.11.06 10:45:52 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2019.11.06 12:56:44 -05'00'

MINIMUM FONT SIZE: 6 PT

GLENMARK PHARMACEUTICALS LTD.		**DATE:**	**PANTONE SHADE NO:** BLACK 364 C 186 C
PRODUCT NAME: Carvedilol Tablets USP 25 mg		**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE52244 **VERSION:** 0919-1		**RA**	Regulatory Text
PHARMACODE:		**QA:**	Entire Text
COUNTRY: USA		**PRODUCTION:**	Machine Suitability
LOCATION: INDORE		**REMARKS:**	
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			

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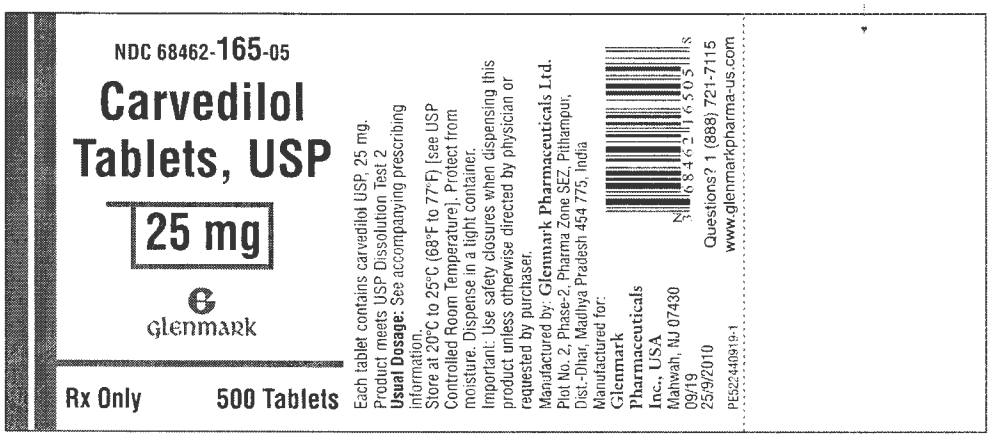
JAR SIZE : 250 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 55 mm

UNVARNISHED AREA
30 mm x 15 mm



May Breedlove
Digitally signed by May Breedlove
Date: 2019.11.06 10:14:15 -05'00'

Donna-Marie Walters
Digitally signed by Donna-Marie Walters
Date: 2019.11.06 10:45:52 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2019.11.06 12:56:44 -05'00'

MINIMUM FONT SIZE: 6 PT

GLENMARK PHARMACEUTICALS LTD.		**DATE:**	**PANTONE SHADE NO:** BLACK 364 C 186 C
PRODUCT NAME: Carvedilol Tablets USP 25 mg		**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE52244 **VERSION:** 0919-1		**RA**	Regulatory Text
PHARMACODE:		**QA:**	Entire Text
COUNTRY: USA		**PRODUCTION:**	Machine Suitability
LOCATION: INDORE			
PACK : LABEL - 500 TABLETS		**REMARKS:**	
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

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

UNVARNISHED AREA
85 mm x 50 mm

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
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com
PE52242/0919-1

May Breedlove
Digitally signed by May Breedlove
Date: 2019.11.06 10:15:18 -05'00'

Donna-Marie Walters
Digitally signed by Donna-Marie Walters
Date: 2019.11.06 10:44:04 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2019.11.06 12:56:14 -05'00'

MINIMUM FONT SIZE: 5.1 PT

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

JAR SIZE : 40 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 30 mm

May Breedlove
Digitally signed by May Breedlove
Date: 2019.11.06 10:11:27 -05'00'

Donna-Marie Walters
Digitally signed by Donna-Marie Walters
Date: 2019.11.06 10:48:54 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2019.11.06 12:58:05 -05'00'

MINIMUM FONT SIZE: 3.9 PT

GLENMARK PHARMACEUTICALS LTD.		**DATE:**	**PANTONE SHADE NO:** BLACK 143 C, 186 C
PRODUCT NAME: Carvedilol Tablets USP 12.5 mg		**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE52249 **VERSION:** 0919-1		**RA**	Regulatory Text
PHARMACODE:		**QA:**	Entire Text
COUNTRY: USA		**PRODUCTION:**	Machine Suitability
LOCATION: INDORE		**REMARKS:**	
PACK : LABEL - 100 TABLETS			
ACTUAL SIZE: 105 mm x 30 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			

Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

Carvedilol Tablets, USP 25mg

NDC: 68462-165-01 (100's Bottles pack Container) & 68462-165-05 (500's Bottles pack Container)

Carvedilol tablets, USP 12.5mg

NDC: 68462-164-01 (100's Bottles pack Container) & 68462-164-05 (500's Bottles pack Container)

Retail Level

01/22/2025

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#:	
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_____.

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Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
CARVEDILOL TAB 25MG	68462-165-05	17230500/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230509/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230526/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230546/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230551/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230603/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230628/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230642/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230645/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230681/500`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230829/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230832/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230854/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230864/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230874/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230876/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230889/500`s pack	03/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230894/500`s pack	03/2025	

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Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
CARVEDILOL TAB 25MG	68462-165-05	17230960/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230964/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230976/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230981/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17230985/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231161/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231171/500`s pack	04/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231315/500`s pack	05/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231318/500`s pack	05/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231332/500`s pack	05/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231333/500`s pack	05/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231365/500`s pack	05/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231539/500`s pack	06/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231563/500`s pack	06/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231653/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231662/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231663/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231680/500`s pack	07/2025	

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Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
CARVEDILOL TAB 25MG	68462-165-05	17231691/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231781/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231782/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231789/500`s pack	07/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231838/500`s pack	08/2025	
CARVEDILOL TAB 25MG	68462-165-05	17231880/500`s pack	08/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232144/500`s pack	09/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232147/500`s pack	09/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232151/500`s pack	09/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232369/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232370/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232408/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232409/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232416/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232504/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232522/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232531/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17232538/500`s pack	11/2025	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
CARVEDILOL TAB 25MG	68462-165-05	17232543/500`s pack	11/2025	
CARVEDILOL TAB 25MG	68462-165-05	17240377/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-05	17240385/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-05	17240415/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-05	17240422/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-05	17240430/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-05	17240510/500`s pack	02/2026	
CARVEDILOL TAB 25MG	68462-165-01	17230551/100`s pack	02/2025	
CARVEDILOL TAB 25MG	68462-165-01	17240377/100`s pack	02/2026	
CARVEDILOL TAB 12.5MG	68462-164-05	17230658/500`s pack	02/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17230814/500`s pack	03/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17230822/500`s pack	03/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231004/500`s pack	04/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231009/500`s pack	04/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231022/500`s pack	04/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231393/500`s pack	05/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231392/500`s pack	05/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231538/500`s pack	06/2025	

Item Description	NDC#	Lot#/ Pack Size	Exp. Date	Total Full/Sealed and Partial/Open Bottle Count
CARVEDILOL TAB 12.5MG	68462-164-05	17231541/500`s pack	06/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231542/500`s pack	06/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231710/500`s pack	07/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231718/500`s pack	07/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231721/500`s pack	07/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231722/500`s pack	07/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17231730/500`s pack	07/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17232169/500`s pack	09/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17232253/500`s pack	10/2025	
CARVEDILOL TAB 12.5MG	68462-164-05	17240220/500`s pack	01/2026	
CARVEDILOL TAB 12.5MG	68462-164-05	17240240/500`s pack	01/2026	
CARVEDILOL TAB 12.5MG	68462-164-05	17240459/500`s pack	02/2026	
CARVEDILOL TAB 12.5MG	68462-164-01	17230814/100`s pack	03/2025	
CARVEDILOL TAB 12.5MG	68462-164-01	17231392/100`s pack	05/2025	
CARVEDILOL TAB 12.5MG	68462-164-01	17232260/100`s pack	10/2025	

If you have any questions regarding this form or product return please contact Inmar at 877-589-8040 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 N131251 / RCL001-25

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URGENT: DRUG RECALL

Carvedilol tablets, USP 25mg NDC: 68462-165-01 (100's Bottles pack Container) & 68462-165-05 (500's Bottles pack Container)

Carvedilol tablets, USP 12.5mg NDC: 68462-164-01 (100's Bottles pack Container) & 68462-164-05 (500's Bottles pack Container)

January 22, 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	17230500	500 bottle pack	02/2025
2.	68462-165-05	17230509	500 bottle pack	02/2025
3.	68462-165-05	17230526	500 bottle pack	02/2025
4.	68462-165-05	17230546	500 bottle pack	02/2025
5.	68462-165-05	17230551	500 bottle pack	02/2025
6.	68462-165-05	17230603	500 bottle pack	02/2025
7.	68462-165-05	17230628	500 bottle pack	02/2025
8.	68462-165-05	17230642	500 bottle pack	02/2025
9.	68462-165-05	17230645	500 bottle pack	02/2025
10.	68462-165-05	17230681	500 bottle pack	02/2025

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S. No.	NDC	Batch #	Pack Size	Expiry
11.	68462-165-05	17230829	500 bottle pack	03/2025
12.	68462-165-05	17230832	500 bottle pack	03/2025
13.	68462-165-05	17230854	500 bottle pack	03/2025
14.	68462-165-05	17230864	500 bottle pack	03/2025
15.	68462-165-05	17230874	500 bottle pack	03/2025
16.	68462-165-05	17230876	500 bottle pack	03/2025
17.	68462-165-05	17230889	500 bottle pack	03/2025
18.	68462-165-05	17230894	500 bottle pack	03/2025
19.	68462-165-05	17230960	500 bottle pack	04/2025
20.	68462-165-05	17230964	500 bottle pack	04/2025
21.	68462-165-05	17230976	500 bottle pack	04/2025
22.	68462-165-05	17230981	500 bottle pack	04/2025
23.	68462-165-05	17230985	500 bottle pack	04/2025
24.	68462-165-05	17231161	500 bottle pack	04/2025
25.	68462-165-05	17231171	500 bottle pack	04/2025
26.	68462-165-05	17231315	500 bottle pack	05/2025
27.	68462-165-05	17231318	500 bottle pack	05/2025
28.	68462-165-05	17231332	500 bottle pack	05/2025
29.	68462-165-05	17231333	500 bottle pack	05/2025
30.	68462-165-05	17231365	500 bottle pack	05/2025

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S. No.	NDC	Batch #	Pack Size	Expiry
31.	68462-165-05	17231539	500 bottle pack	06/2025
32.	68462-165-05	17231563	500 bottle pack	06/2025
33.	68462-165-05	17231653	500 bottle pack	07/2025
34.	68462-165-05	17231662	500 bottle pack	07/2025
35.	68462-165-05	17231663	500 bottle pack	07/2025
36.	68462-165-05	17231680	500 bottle pack	07/2025
37.	68462-165-05	17231691	500 bottle pack	07/2025
38.	68462-165-05	17231781	500 bottle pack	07/2025
39.	68462-165-05	17231782	500 bottle pack	07/2025
40.	68462-165-05	17231789	500 bottle pack	07/2025
41.	68462-165-05	17231838	500 bottle pack	08/2025
42.	68462-165-05	17231880	500 bottle pack	08/2025
43.	68462-165-05	17232144	500 bottle pack	09/2025
44.	68462-165-05	17232147	500 bottle pack	09/2025
45.	68462-165-05	17232151	500 bottle pack	09/2025
46.	68462-165-05	17232369	500 bottle pack	11/2025
47.	68462-165-05	17232370	500 bottle pack	11/2025
48.	68462-165-05	17232408	500 bottle pack	11/2025
49.	68462-165-05	17232409	500 bottle pack	11/2025
50.	68462-165-05	17232416	500 bottle pack	11/2025

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S. No.	NDC	Batch #	Pack Size	Expiry
51.	68462-165-05	17232504	500 bottle pack	11/2025
52.	68462-165-05	17232522	500 bottle pack	11/2025
53.	68462-165-05	17232531	500 bottle pack	11/2025
54.	68462-165-05	17232538	500 bottle pack	11/2025
55.	68462-165-05	17232543	500 bottle pack	11/2025
56.	68462-165-05	17240377	500 bottle pack	02/2026
57.	68462-165-05	17240385	500 bottle pack	02/2026
58.	68462-165-05	17240415	500 bottle pack	02/2026
59.	68462-165-05	17240422	500 bottle pack	02/2026
60.	68462-165-05	17240430	500 bottle pack	02/2026
61.	68462-165-05	17240510	500 bottle pack	02/2026

For Carvedilol tablets, USP 25 mg **100 bottle pack**

Sr. No.	NDC Number	Batch	Pack size	Exp. Date
1.	68462-165-01	17230551	100 bottle pack	02/2025
2.	68462-165-01	17240377	100 bottle pack	02/2026

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

Sr. No.	NDC Number	Batch	Pack size	Exp. Date
1.	68462-164-05	17230658	500 bottle pack	02/2025

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
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Sr. No.	NDC Number	Batch	Pack size	Exp. Date
2.	68462-164-05	17230814	500 bottle pack	03/2025
3.	68462-164-05	17230822	500 bottle pack	03/2025
4.	68462-164-05	17231004	500 bottle pack	04/2025
5.	68462-164-05	17231009	500 bottle pack	04/2025
6.	68462-164-05	17231022	500 bottle pack	04/2025
7.	68462-164-05	17231393	500 bottle pack	05/2025
8.	68462-164-05	17231392	500 bottle pack	05/2025
9.	68462-164-05	17231538	500 bottle pack	06/2025
10.	68462-164-05	17231541	500 bottle pack	06/2025
11.	68462-164-05	17231542	500 bottle pack	06/2025
12.	68462-164-05	17231710	500 bottle pack	07/2025
13.	68462-164-05	17231718	500 bottle pack	07/2025
14.	68462-164-05	17231721	500 bottle pack	07/2025
15.	68462-164-05	17231722	500 bottle pack	07/2025
16.	68462-164-05	17231730	500 bottle pack	07/2025
17.	68462-164-05	17232169	500 bottle pack	09/2025
18.	68462-164-05	17232253	500 bottle pack	10/2025
19.	68462-164-05	17240220	500 bottle pack	01/2026
20.	68462-164-05	17240240	500 bottle pack	01/2026

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Sr. No.	NDC Number	Batch	Pack size	Exp. Date
21.	68462-164-05	17240459	500 bottle pack	02/2026

For Carvedilol tablets, USP 12.5 mg **100 bottle pack**

Sr. No.	NDC Number	Batch	Pack size	Exp. Date
1.	68462-164-01	17230814	100 bottle pack	03/2025
2.	68462-164-01	17231392	100 bottle pack	05/2025
3.	68462-164-01	17232260	100 bottle pack	10/2025

The recall to the retail level of the above identified product batches for Carvedilol tablets USP, 25 mg and 12.5 mg have been initiated out of an abundance of caution due to the presence of a nitrosamine, N-Nitroso Carvedilol Impurity-1 (NNCI) above the current Acceptable Intake Level in certain batches. To date, Glenmark has not received any reports of adverse events related to this recall.

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. Although long-term ingestion of certain nitrosamines may be associated with a potential increased cancer risk in humans, there is no immediate risk to patients taking this medication.

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 30 March, 2023.

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

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 **877-589-8040**

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,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan Thomas Callaghan Digitally signed by Thomas Callaghan Date: 2025.01.22 12:18:46 -05'00'

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

Product labels

- 12.5 mg , 100's Count

JAR SIZE : 40 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 30 mm

May Breedlove
Digitally signed by May Breedlove
Date: 2019.11.06 10:11:27 -05'00'

Donna-Marie Walters
Digitally signed by Donna-Marie Walters
Date: 2019.11.06 10:48:54 -05'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2019.11.06 12:58:05 -05'00'

MINIMUM FONT SIZE: 3.9 PT

GLENMARK PHARMACEUTICALS LTD.		DATE:	PANTONE SHADE NO: BLACK 143 C 186 C	
PRODUCT NAME: Carvedilol Tablets USP 12.5 mg		PKG. DEV.:	Item code, Version, Consistency of Design, Warning Area, Pack size, Dimensions & Layout	
ITEM CODE: PE52249 VERSION: 0919-1		RA	Regulatory Text	
PHARMACODE:		QA:	Before Text	
COUNTRY: USA		PRODUCTION:	Machine Suitability	
LOCATION: INDORE		REMARKS:		
PACK : LABEL - 100 TABLETS				
ACTUAL SIZE: 105 mm x 30 mm				
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITACY PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED				

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

- 12.5 mg , 500's Count

JAR SIZE : 180 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 50 mm

May Breedlove Digitally signed by May Breedlove Date: 2019.11.06 10:15:18 -05'00'

Donna-Marie Walters Digitally signed by Donna-Marie Walters Date: 2019.11.06 10:44:04 -05'00'

Carole Capella Digitally signed by Carole Capella Date: 2019.11.06 12:56:14 -05'00'

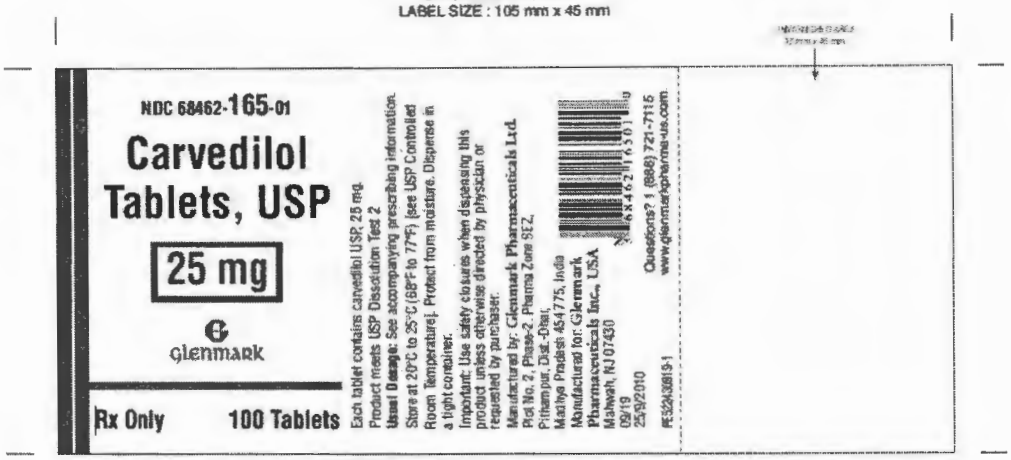
MINIMUM FONT SIZE: 5.1 PT

GLENMARK PHARMACEUTICALS LTD.			
PRODUCT NAME: Carvedilol Tablets USP 12.5 mg	DATE:	PANTONE SHADE NO:	BLACK 143 C 186 C
ITEM CODE: PE52242 VERSION: 0919-1	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
PHARMACODE:	RA	Regulatory Text	
COUNTRY: USA	QA:	Entire Text	
LOCATION: INDORE	PRODUCTION:	Machine Suitability	
PACK : LABEL - 500 TABLETS	REMARKS:		
ACTUAL SIZE: 130 mm x 50 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITACI/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED			

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

- 25 mg , 100's Count

JAR SIZE : 60 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 45 mm



May Breedlove Digitally signed by May Breedlove Date: 2019.11.06 10:14:51 -05'00'

Donna-Marie Walters Digitally signed by Donna-Marie Walters Date: 2019.11.06 10:45:06 -05'00'

Carole Capella Digitally signed by Carole Capella Date: 2019.11.06 12:56:30 -05'00'

MINIMUM FONT SIZE: 4.5 PT

GLENMARK PHARMACEUTICALS LTD.	**DATE:**	**PANTONE SHADE NO:** BLACK 186 C	364 C
PRODUCT NAME: Carvedilol Tablets USP 25 mg	**PKG. DEV.:**	Item code, Version, Consistency of Design, Overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE52243 **VERSION:** 0919-1	**RA**	Regulatory Text	
PHARMACODE:	**QA:**	Entire Text	
COUNTRY: USA	**PRODUCTION:**	Machine Suitability	
LOCATION: INDORE	**REMARKS:**		
PACK : LABEL - 100 TABLETS			
ACTUAL SIZE: 105 mm x 45 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITACI)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED			

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

the symptoms of low blood sugar, especially a fast heartbeat.
- Carvedilol tablets may mask the symptoms of hyperthyroidism (overactive thyroid).
- **Worsening of severe allergic reactions.**
- Rare but serious allergic reactions (including hives or swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing) have happened in patients who were on carvedilol tablets. These reactions can be life-threatening.

Other side effects of carvedilol tablets include shortness of breath, weight gain, diarrhea, and fewer tears or dry eyes that become bothersome if you wear contact lenses.

Call your doctor if you have any side effects that bother you or don't go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Carvedilol Tablets?

- Store carvedilol tablets at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
- Safely, throw away carvedilol tablets that are out of date or no longer needed.
- Keep carvedilol tablets and all medicines out of the reach of children.

General Information about Carvedilol Tablets

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use carvedilol tablets for a condition for which it was not prescribed. Do not give carvedilol tablets to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about carvedilol tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about carvedilol tablets that is written for healthcare professionals. You can also find out more about carvedilol tablets by calling 1 (888) 721-7115. This call is free.

What are the ingredients in Carvedilol Tablets?

Active Ingredient: carvedilol.

Fetal/Neonatal Adverse Reactions: Neonates of women with hypertension who are treated with beta-blockers during the third trimester of pregnancy may be at increased risk for hypotension, bradycardia, hypoglycemia, and respiratory depression. Observe newborns for symptoms of hypotension, bradycardia, hypoglycemia, and respiratory depression and manage accordingly.

Data

Animal Data: Studies performed in rats and rabbits given carvedilol during fetal organogenesis revealed increased post-implantation loss in rats at a maternally toxic dose of 300 mg per kg per day (50 times the MRHD as mg per m^2) and in rabbits (in the absence of maternal toxicity) at doses of 75 mg per kg per day (25 times the MRHD as mg per m^2). In the rats, there was also a decrease in fetal body weight at 300 mg per kg per day (50 times the MRHD as mg per m^2) accompanied by an increased incidence of fetuses with delayed skeletal development. In rats, the no-effect level for embryo-fetal toxicity was 60 mg per kg per day (10 times the MRHD as mg per m^2); in rabbits, it was 15 mg per kg per day (5 times the MRHD as mg per m^2). In a pre-and post-natal development study in rats administered carvedilol from late gestation through lactation, increased embryo-lethality was observed at a maternally toxic dose of 200 mg per kg per day (approximately 32 times the MRHD as mg per m^2), and pup mortality and delays in physical growth/development were observed at 60 mg per kg per day (10 times the MRHD as mg per m^2) in the absence of maternal toxicity. The no-effect level was 12 mg per kg per day (2 times the MRHD as mg per m^2). Carvedilol was present in fetal rat tissue.

8.2 Lactation

Risk Summary

There are no data on the presence of carvedilol in human milk, the effects on the breastfed infant, or the effects on milk production. Carvedilol is present in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for carvedilol and any potential adverse effects on the breastfed infant from carvedilol or from the underlying maternal condition.

8.4 Pediatric Use

Effectiveness of carvedilol in patients younger than 18 years has not been established.

In a double-blind trial, 161 children (mean age: 6 years; range: 2 months to 17 years; 45% younger than 2 years) with chronic heart failure (NYHA class II-IV, left ventricular ejection fraction less than 40% for children with a systemic left ventricle (LV), and moderate-severe ventricular dysfunction qualitatively by echo for those with a systemic ventricle that was not an LV) who were receiving standard background treatment were randomized to placebo or to 2 dose levels of carvedilol. These dose levels produced placebo-corrected heart rate reduction of 4 to 6 heart beats per minute, indicative of β-blockade activity. Exposure appeared to be lower in pediatric subjects than adults. After 8 months of follow-up, there was no significant effect of treatment on clinical outcomes. Adverse reactions in this trial that occurred in greater than 10% of subjects treated with carvedilol and at twice the rate of placebo-treated subjects included chest pain (17% versus 6%), dizziness (13% versus 2%), and dyspnea (11% versus 0%).

8.5 Geriatric Use

Of the 765 subjects with heart failure randomized to carvedilol in U.S. clinical trials, 31% (235) were aged 65 years or older, and 7.3% (56) were aged 75 years or older. Of the 1,156 subjects randomized to carvedilol in a long-term, placebo-controlled trial in severe heart failure, 47% (547) were aged 65 years or older, and 15% (174) were aged 75 years or older. Of 3,025 subjects receiving carvedilol in heart failure trials worldwide, 42% were aged 65 years or older.

Of the 975 subjects with myocardial infarction randomized to carvedilol in the CAPRICORN trial, 48% (468) were aged 65 years or older, and 11% (111) were aged 75 years or older.

Of the 2,065 hypertensive subjects in U.S. clinical trials of efficacy or safety who were treated with carvedilol, 21% (436) were aged 65 years or older. Of 3,722 subjects receiving carvedilol in hypertension clinical trials conducted worldwide, 24% were aged 65 years or older.

With the exception of dizziness in hypertensive subjects (incidence 8.8% in the elderly versus 6% in younger subjects), no overall differences in the safety or effectiveness (see Figures 2 and 4) were observed between the older subjects and younger subjects in each of these populations. Similarly, other reported clinical experience has not identified differences in responses between the elderly and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

10 OVERDOSAGE

Overdosage may cause severe hypotension, bradycardia, cardiac insufficiency, cardiogenic shock, and cardiac arrest. Respiratory problems, bronchospasms, vomiting, lapses of consciousness, and generalized seizures may also occur.

The patient should be placed in a supine position and, where necessary, kept under observation and treated under intensive-care conditions. The following agents may be administered:

For excessive bradycardia: Atropine, 2 mg IV.

To support cardiovascular function: Glucagon, 5 to 10 mg IV rapidly over 30 seconds, followed by a continuous infusion of 5 mg per hour; sympathomimetics (dobutamine, isoprenaline, adrenaline) at doses according to body weight and effect.

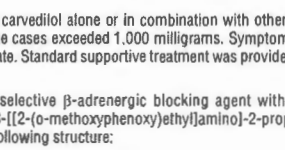
If peripheral vasodilation dominates, it may be necessary to administer adrenaline or noradrenaline with continuous monitoring of circulatory conditions. For therapy-resistant bradycardia, pacemaker therapy should be performed. For bronchospasm, β-sympathomimetics (as aerosol or IV) or aminophylline IV should be given. In the event of seizures, slow IV injection of diazepam or clonazepam is recommended.

NOTE: In the event of severe intoxication where there are symptoms of shock, treatment with antidotes must be continued for a sufficiently long period of time consistent with the 7 to 10 hour half-life of carvedilol.

Cases of overdosage with carvedilol alone or in combination with other drugs have been reported. Quantities ingested in some cases exceeded 1,000 milligrams. Symptoms experienced included low blood pressure and heart rate. Standard supportive treatment was provided and individuals recovered.

11 DESCRIPTION

Carvedilol, USP is a nonselective β-adrenergic blocking agent with α_1-blocking activity. It is (±)-1-(Carbazol-4-yloxy)-3-[[2-(o-methoxyphenoxy)ethyl]amino]-2-propanol. Carvedilol, USP is a racemic mixture with the following structure:



Carvedilol tablets, USP are film-coated tablets containing 3.125 mg, 6.25 mg, 12.5 mg or 25 mg of carvedilol. The 3.125 mg, 6.25 mg and 25 mg tablets are white film-coated circular shaped tablets. The 12.5 mg tablets are white film-coated capsule shaped tablets. Inactive ingredients consist of colloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, povidone and titanium dioxide.

Carvedilol, USP is a white to off-white powder with a molecular weight of 406.5 g/mol and a molecular formula of $C_{24}H_{26}N_2O_4$. It is freely soluble in dimethylsulfoxide; soluble in methylene chloride and

Rifampin

In a pharmacokinetic trial conducted in 8 he decreased the AUC and C_{max} of carvedilol by

Torsemide

In a trial of 12 healthy subjects, combine and torsemide 5 mg once daily for 5 day pharmacokinetics compared with administra

Warfarin

Carvedilol (12.5 mg twice daily) did not have did not alter the pharmacokinetics of R(+)- with warfarin in 9 healthy volunteers.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impai

In 2-year studies conducted in rats given car MRHD as mg per m^2) or in mice given up to m^2), carvedilol had no carcinogenic effect.

Carvedilol was negative when tested in a b the CHO/HGPRT assays for mutagenicity an lymphocyte cell tests for clastogenicity.

In a combined fertility/developmental/post-n 300 mg per kg per day) orally by gavage for and weaning for females and for 62 days pri mg per kg per day (greater than or equal to 5 adult rats (sedation, reduced weight gain) ar matings, prolonged mating time, fewer corpo and delays in physical growth/development. fertility was 60 mg per kg per day (10 times

14 CLINICAL STUDIES

14.1 Heart Failure

A total of 6,975 subjects with mild to severe of carvedilol.

Mild-to-Moderate Heart Failure

Carvedilol was studied in 5 multicenter, placeb trial) involving subjects with mild-to-modera

Four U.S. multicenter, double-blind, placebo-c to carvedilol) with NYHA class II-III heart fail vast majority were on digitalis, diuretics, and the trials based upon exercise ability. An Aust enrolled 415 subjects (half randomized to carve subjects expected to undergo cardiac transp follow-up. All randomized subjects had tolera

In each trial, there was a primary end point, ei tolerance (2 U.S. trials meeting enrollment goa secondary end points specified in these trial: global assessments, and cardiovascular hos included the sum of deaths and total cardiova end points of a trial do not show a significant to the other results is complex, and such valu

The results of the U.S. and Australia-New Zea

Slowing Progression of Heart Failure: One l end point the sum of cardiovascular mortality in heart failure medications. Heart failure pro 7 months, by 48% (P = 0.008).

In the Australia-New Zealand trial, death and 18 to 24 months. In the 3 largest U.S. trials, 39%, and 49%, nominally statistically significa were statistically borderline.

Functional Measures: None of the multicente but all such trials had it as a secondary end in NYHA class in all trials. Exercise tolerance statistically significant effect found.

Subjective Measures: Health-related quality primary end point in 1 trial), was unaffected by assessments showed significant improvemen

Mortality: Death was not a pre-specified end p these 4 U.S. trials, mortality was reduced, nor

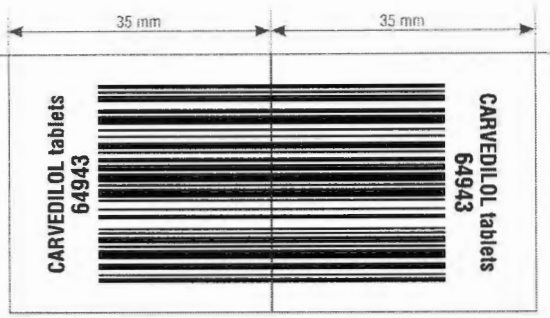
The COMET Trial

In this double-blind trial, 3,029 subjects with fraction less than or equal to 35%) were rand twice daily) or immediate-release metoprolol t of the subjects was approximately 62 years, 8 fraction at baseline was 26%. Approximately 9 Concomitant treatment included diuretics (99 antagonists (11%), and "statin" lipid-lowering years. The mean dose of carvedilol was 42 mg

The trial had 2 primary end points: all-cause m for any reason. The results of COMET are prese of the statistical weight and was the primary de in the subjects treated with carvedilol and wa = 0.0017; hazard ratio = 0.83, 95% CI 0.74 to reduction in cardiovascular death. The differen end point was not significant (P = 0.122). Th and 6.6 years with immediate-release metopro

Table 3. Results of COMET

End Point	Carved N=1,5
All-cause mortality	34%



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CARVEDILOL TABLETS safely and effectively. See full prescribing information for CARVEDILOL TABLETS.

CARVEDILOL tablets for oral use
Initial U.S. Approval: 1995

INDICATIONS AND USAGE

Carvedilol tablets are an alpha-/beta-adrenergic blocking agent indicated for the treatment of:

- mild to severe chronic heart failure (1.1)
- left ventricular dysfunction following myocardial infarction in clinically stable patients (1.2)
- hypertension (1.3)

DOSAGE AND ADMINISTRATION

Take with food. Individualize dosage and monitor during up-titration. (2)

- Heart failure: Start at 3.125 mg twice daily and increase to 6.25, 12.5, and then 25 mg twice daily over intervals of at least 2 weeks. Maintain lower doses if higher doses are not tolerated. (2.1)
- Left ventricular dysfunction following myocardial infarction: Start at 6.25 mg twice daily and increase to 12.5 mg then 25 mg twice daily after intervals of 3 to 10 days. A lower starting dose or slower titration may be used. (2.2)
- Hypertension: Start at 6.25 mg twice daily and increase if needed for blood pressure control to 12.5 mg and then 25 mg twice daily over intervals of 1 to 2 weeks. (2.3)

DOSAGE FORMS AND STRENGTHS

Tablets: 3.125 mg, 6.25 mg, 12.5 mg, 25 mg (3)

CONTRAINDICATIONS

- Bronchial asthma or related bronchospastic conditions. (4)
- Second- or third-degree AV block. (4)
- Sick sinus syndrome. (4)
- Severe bradycardia (unless permanent pacemaker in place). (4)
- Patients in cardiogenic shock or decompensated heart failure requiring the use of IV inotropic therapy. (4)
- Severe hepatic impairment. (2.4, 4)
- History of serious hypersensitivity reaction (e.g., Stevens-Johnson syndrome, anaphylactic reaction, angioedema) to any component of this medication or other medications containing carvedilol. (4)

WARNINGS AND PRECAUTIONS

- Acute exacerbation of coronary artery disease upon cessation of therapy: Do not abruptly discontinue. (5.1)
- Bradycardia, hypotension, worsening heart failure/fluid retention may occur. Reduce the dose as needed. (5.2, 5.3, 5.4)
- Non-allergic bronchospasm (e.g., chronic bronchitis and emphysema). Avoid β-blockers. (4) However, if deemed necessary, use with caution and at lowest effective dose. (5.5)
- Diabetes: May mask symptoms of hypoglycemia and alter glucose levels; monitor. (5.5)
- Diabetes: Monitor glucose as β-blockers may mask symptoms of hypoglycemia or worsen hyperglycemia. (5.6)

ADVERSE REACTIONS

Most common adverse events (6.1):

- Heart failure and left ventricular dysfunction following myocardial infarction (≤ 10%): Dizziness, fatigue, hypotension, diarrhea, hyperglycemia, asthenia, bradycardia, weight increase.
- Hypertension (≥ 5%): Dizziness.

To report SUSPECTED ADVERSE REACTIONS, contact Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- CYP P450 2D6 enzyme inhibitors may increase and rifampin may decrease carvedilol levels. (7.1, 7.5)
- Hypotensive agents (e.g., reserpine, MAO inhibitors, clonidine) may increase the risk of hypotension and/or severe bradycardia. (7.4)
- Cyclosporine or digoxin levels may increase. (7.3, 7.4)
- Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia. (7.4)
- Amiodarone may increase carvedilol levels resulting in further slowing of the heart rate or cardiac conduction. (7.6)
- Verapamil- or diltiazem-type calcium channel blockers may affect ECG and/or blood pressure. (7.7)
- Insulin and oral hypoglycemics action may be enhanced. (7.8)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 08/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

Gastrointestinal
Diarrhea
Nausea
Vomiting
Metabolic
Hyperglycemia
Weight increase
BUN increased
NPN increased
Hypercholesterole
Edema peripheral
Musculoskeletal
Arthralgia
Respiratory
Cough increased
Rales
Vision
Vision abnormal

Cardiac failure and dysp
subjects who received p

The following adverse
equal to 3% and more f
with mild-to-moderate

Incidence greater than

Body as a Whole: Allerg

Cardiovascular: Fluid ov
hypertension.

Central and Peripheral

Gastrointestinal: Melen

Liver and Biliary Syste

Metabolic and Nutritiona
glycosuria, hypervolem
increased.

Musculoskeletal: Muscl

Platelet, Bleeding, and

Psychiatric: Somnolenc

Reproductive, male: Im

Special Senses: Blurred

Urinary System: Renal i

Left Ventricular Dysfun
Carvedilol has been evalu
dysfunction in the CAPP
received placebo. Appr
53% received carvedilol
and 12.8 months with c

The most common adv
with the profile of the dr
adverse events reporte
carvedilol were dyspnea
a frequency of greater
flu syndrome, cerebro
gastrointestinal pain, ar
were similar in both grou
1% and occurring more

Hypertension:
Carvedilol has been eva
trials and in 2,976 sub
population received car
with carvedilol were of
carvedilol in doses up
carvedilol discontinued
overall difference in disc
for postural hypotensio
controlled trials increas
only be distinguished fo
increased from 6.25 mg

Table 2 shows adverse
with an incidence of gre
in drug-treated subjects

Table 2. Adverse Event
≥ 1%, Regardless of C

Body System/ Adverse
Cardiovascular
Bradycardia
Postural hypotensi
Peripheral edema
Central Nervous Syste
Dizziness
Insomnia
Gastrointestinal
Diarrhea
Hematologic
Thrombocytopenia
Metabolic
Hypertriglyceriden