

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you of that Glenmark is initiating a recall to the Retail level involving the following prescription product for Carvedilol tablets, USP 25 mg 500 bottle pack.

The recall to the retail level of the below 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.

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
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
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
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.	NDC Number	Batch	Pack size	Exp. Date
No.				
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.	NDC Number	Batch	Pack size	Exp. Date
No.				
1.	68462-164-05	17230658	500 bottle pack	02/2025
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
21.	68462-164-05	17240459	500 bottle pack	02/2026

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

Sr.	NDC Number	Batch	Pack size	Exp. Date
No.				
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