

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 that Glenmark is initiating a recall to the Retail level involving Carvedilol Tablets USP. The recall to the retail level of the below-identified Carvedilol Tablets USP 3.125mg, 6.25mg, 12.5mg, and 25mg batches have been initiated out of an abundance of caution due to the presence of a nitrosamine, 'N-Nitroso Carvedilol I' Impurity 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. There is no immediate risk to patients taking the medication.

Carvedilol Tablets USP 3.125mg (100's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-162-01	19231450	100's Tablets in Container	Mar-25
2	68462-162-01	19233345	100's Tablets in Container	Jul-25
3	68462-162-01	19234275	100's Tablets in Container	Sep-25
4	68462-162-01	19240280	100's Tablets in Container	Dec-25

Carvedilol Tablets USP 3.125mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-162-05	19231450	500's Tablets in Container	Mar-25
2	68462-162-05	19231464	500's Tablets in Container	Mar-25
3	68462-162-05	19231471	500's Tablets in Container	Mar-25
4	68462-162-05	19231493	500's Tablets in Container	Mar-25
5	68462-162-05	19232083	500's Tablets in Container	Apr-25
6	68462-162-05	19232103	500's Tablets in Container	Apr-25

7	68462-162-05	19232658	500's Tablets in Container	Jun-25
8	68462-162-05	19233328	500's Tablets in Container	Jul-25
9	68462-162-05	19233343	500's Tablets in Container	Jul-25
10	68462-162-05	19233344	500's Tablets in Container	Jul-25
11	68462-162-05	19233345	500's Tablets in Container	Jul-25
12	68462-162-05	19234275	500's Tablets in Container	Sep-25
13	68462-162-05	19240280	500's Tablets in Container	Dec-25
14	68462-162-05	19234843	500's Tablets in Container	Nov-25
15	68462-162-05	19235039	500's Tablets in Container	Nov-25
16	68462-162-05	19240296	500's Tablets in Container	Dec-25

Carvedilol Tablets USP 6.25mg (100's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-163-01	19231618	100's Tablets in Container	Mar-25
2	68462-163-01	19232064	100's Tablets in Container	Apr-25
3	68462-163-01	19232324	100's Tablets in Container	May-25
4	68462-163-01	19233369	100's Tablets in Container	Jul-25
5	68462-163-01	19234162	100's Tablets in Container	Sep-25
6	68462-163-01	19240543	100's Tablets in Container	Jan-26

Carvedilol Tablets USP 6.25mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-163-05	19231174	500's Tablets in Container	Feb-25

2	68462-163-05	19231199	500's Tablets in Container	Feb-25
3	68462-163-05	19231517	500's Tablets in Container	Mar-25
4	68462-163-05	19231527	500's Tablets in Container	Mar-25
5	68462-163-05	19231566	500's Tablets in Container	Mar-25
6	68462-163-05	19231568	500's Tablets in Container	Mar-25
7	68462-163-05	19231595	500's Tablets in Container	Mar-25
8	68462-163-05	19231618	500's Tablets in Container	Mar-25
9	68462-163-05	19231634	500's Tablets in Container	Mar-25
10	68462-163-05	19231638	500's Tablets in Container	Mar-25
11	68462-163-05	19232043	500's Tablets in Container	Apr-25
12	68462-163-05	19232051	500's Tablets in Container	Apr-25
13	68462-163-05	19232064	500's Tablets in Container	Apr-25
14	68462-163-05	19232322	500's Tablets in Container	May-25
15	68462-163-05	19232324	500's Tablets in Container	May-25
16	68462-163-05	19232365	500's Tablets in Container	May-25
17	68462-163-05	19232380	500's Tablets in Container	May-25
18	68462-163-05	19232389	500's Tablets in Container	May-25
19	68462-163-05	19232736	500's Tablets in Container	Jun-25
20	68462-163-05	19232743	500's Tablets in Container	Jun-25
21	68462-163-05	19232746	500's Tablets in Container	Jun-25
22	68462-163-05	19232756	500's Tablets in Container	Jun-25

23	68462-163-05	19232757	500's Tablets in Container	Jun-25
24	68462-163-05	19233369	500's Tablets in Container	Jul-25
25	68462-163-05	19233371	500's Tablets in Container	Jul-25
26	68462-163-05	19233405	500's Tablets in Container	Jul-25
27	68462-163-05	19233416	500's Tablets in Container	Jul-25
28	68462-163-05	19234162	500's Tablets in Container	Sep-25
29	68462-163-05	19234183	500's Tablets in Container	Sep-25
30	68462-163-05	19234192	500's Tablets in Container	Sep-25
31	68462-163-05	19234204	500's Tablets in Container	Sep-25
32	68462-163-05	19234223	500's Tablets in Container	Sep-25
33	68462-163-05	19234243	500's Tablets in Container	Sep-25
34	68462-163-05	19234263	500's Tablets in Container	Sep-25
35	68462-163-05	19240223	500's Tablets in Container	Dec-25
36	68462-163-05	19240543	500's Tablets in Container	Jan-26
37	68462-163-05	19231448	500's Tablets in Container	Mar-25
38	68462-163-05	19231164	500's Tablets in Container	Feb-25
39	68462-163-05	19234165	500's Tablets in Container	Sep-25
40	68462-163-05	19234242	500's Tablets in Container	Sep-25
41	68462-163-05	19234743	500's Tablets in Container	Nov-25
42	68462-163-05	19234774	500's Tablets in Container	Nov-25
43	68462-163-05	19234993	500's Tablets in Container	Nov-25

44	68462-163-05	19240203	500's Tablets in Container	Dec-25
45	68462-163-05	19240211	500's Tablets in Container	Dec-25
46	68462-163-05	19240214	500's Tablets in Container	Dec-25
47	68462-163-05	19240247	500's Tablets in Container	Dec-25
48	68462-163-05	19240249	500's Tablets in Container	Dec-25
49	68462-163-05	19240272	500's Tablets in Container	Dec-25
50	68462-163-05	19240319	500's Tablets in Container	Dec-25

Carvedilol Tablets USP 12.5mg (500's Tablets)

s. No.	NDC	Batch No.	Pack Style	Expiry Date
1	68462-164-05	19231899	500's Tablets in Container	Apr-25
2	68462-164-05	19231922	500's Tablets in Container	Apr-25
3	68462-164-05	19231927	500's Tablets in Container	Apr-25
4	68462-164-05	19231967	500's Tablets in Container	Apr-25
5	68462-164-05	19231979	500's Tablets in Container	Apr-25
6	68462-164-05	19232226	500's Tablets in Container	May-25
7	68462-164-05	19232234	500's Tablets in Container	May-25
8	68462-164-05	19232265	500's Tablets in Container	May-25
9	68462-164-05	19232271	500's Tablets in Container	May-25
10	68462-164-05	19232758	500's Tablets in Container	Jun-25
11	68462-164-05	19232759	500's Tablets in Container	Jun-25
12	68462-164-05	19232762	500's Tablets in Container	Jun-25

13	68462-164-05	19232788	500's Tablets in Container	Jun-25
----	--------------	----------	----------------------------	--------

Carvedilol Tablets USP 25mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-165-05	19231107	500's Tablets in Container	Feb-25
2	68462-165-05	19231114	500's Tablets in Container	Feb-25
3	68462-165-05	19231152	500's Tablets in Container	Feb-25
4	68462-165-05	19234866	500's Tablets in Container	Jan-26