*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 3.125mg, 12.5mg, and 25mg 100s and 500s Container pack (Tablets).

The recall to the retail level of the above-identified Carvedilol Tablets USP 3.125mg, 12.5mg, and 25mg batches have been initiated due to the presence of a nitrosamine, 'N-Nitroso Carvedilol I' Impurity above the current Acceptable Intake Level. 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, but there is no immediate risk to patients taking the medication and the probability of serious adverse health consequences is remote.

Carvedilol Tablets USP 3.125mg (100's Tablets)

| Sr. No. | NDC Code | Batch Number | Pack Size | Expiry Date |
|---|---|---|---|---|
| 1 | 68462-162-01 | 19242272 | 100's Tablets in Container | May-26 |

Carvedilol Tablets USP 3.125mg (500's Tablets)

| Sr. No. | NDC Code | Batch Number | Pack Size | Expiry Date |
|---|---|---|---|---|
| 1 | 68462-162-05 | 19242274 | 500's Tablets in Container | May-26 |
| 2 | 68462-162-05 | 19242275 | 500's Tablets in Container | May-26 |
| 3 | 68462-162-05 | 19242272 | 500's Tablets in Container | May-26 |

Carvedilol Tablets USP 12.5mg (500's Tablets)

| Sr. No. | NDC Code | Batch Number | Pack Size | Expiry Date |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1 | 68462-164-05 | 19243202 | 500's Tablets in Container | Jul-26 |

Carvedilol Tablets USP 25mg (500’s Tablets)

| Sr. No. | NDC Code | Batch Number | Pack Size | Expiry Date |
|---|---|---|---|---|
| 1 | 68462-165-05 | 19243104 | 500's Tablets in Container | Jul-26 |