

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 a product recall involving Carvedilol Tablets, USP, 12.5 mg. This market recall has been initiated by Glenmark Pharmaceuticals Inc. due to the presence of a nitrosamine, 'N-Nitroso Carvedilol I' Impurity, above the current Acceptable Intake Level. 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.

Glenmark Pharmaceuticals Inc. began shipping this product on February 10, 2025.

PRODUCT: Carvedilol Tablets, USP, 12.5 mg 100 Unit Doses (10 x 10 blister packs)

BRAND NAME: Major®

NDC NUMBER: 0904-7307-61

LOT NUMBER: T05693

EXPIRATION DATE: 03/2026