

Viatriis Pharmaceuticals LLC is initiating a drug recall to the RETAIL LEVEL of one (1) lot of Cardura XL (doxazosin) extended-release tablets, 4mg and one (1) lot of Cardura XL (doxazosin) extended release tablets, 8mg packaged in 30 count bottles.

Those lots were sold and distributed by Viatriis Pharmaceuticals LLC between August 23, 2023 and March 28, 2024.

Viatriis Pharmaceuticals LLC was formerly known as Pfizer Pharmaceuticals LLC, and the lots being recalled are labeled as Pfizer product.

These lots are being recalled due to out of specification results obtained for the impurity compound B during stability testing.

The potential risk to the patient arising from this issue is considered negligible.

To date, there are no reports of relevant adverse events/product complaints for Cardura XL 4 mg and 8 mg tablets (batches 8163764 and 8163765).

CARDURA XL is an alpha1 adrenergic antagonist indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia.

NDC#	Material Description/ Strength	Size	Lot No.	Expiry
0049-2040-10	Cardura XL (doxazosin) extended release tablets 4mg	Bottles of 30 tablets	8163764	March 2025
0049-2080-10	Cardura XL (doxazosin) extended release tablets 8mg	Bottles of 30 tablets	8163765	March 2025