

Drug Recall

DATE OF RECALL: October 25, 2022

DRUG NAME: Quinapril and Hydrochlorothiazide 20mg/12.5mg Tablets

RECALLING FIRM: Aurobindo Pharma USA, Inc

REASON FOR RECALL: This recall was issued due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril above the proposed interim limit.

FDA LINK: <u>Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Recall of Two (2) Lots of Quinapril and Hydrochlorothiazide Tablets USP 20mg/12.5mg, Due to the Detection of N-Nitroso Quinapril Impurity | FDA</u>

OTHER DETAILS: See FDA Link

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Quinapril and Hydrochlorothiazide	65862-0162-90	QE2021005-A	01/2023
20mg/12.5mg Tablets		QE2021010-A	