Quinapril/HCTZ 20mg/12.5mg

On October 24, 2022, East Windsor, New Jersey, Aurobindo Pharma USA, Inc. has initiated a voluntary recall of two (2) lots (refer table below) of Quinapril and Hydrochlorothiazide Tablets USP 20mg / 12.5mg, to the consumer level from the US market due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril above the proposed interim limit.

NDC No.	Product Name, strength, and pack	Lot number	Expiry
65862-162-90	Quinapril and Hydrochlorothiazide Tablets USP, 20mg / 12.5mg, 90's HDPE bottle	QE2021005-A	01/2023
		QE2021010-A	

Risk Statement: Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.

Quinapril and Hydrochlorothiazide Tablets, USP are fixed-combination tablet that combines an angiotensin-converting enzyme (ACE) inhibitor, quinapril hydrochloride, and a thiazide diuretic, hydrochlorothiazide. This product is indicated for the treatment of hypertension, to lower blood pressure. Patients should contact their doctor or health care provider about whether to continue taking their medication, or whether to consider an alternative treatment prior to returning their medication.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Aurobindo Pharma USA, Inc. at:

- 1-866-850-2876 (Option 2), 24 hours per day, 7 days per week; or
- pvg@aurobindousa.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Any general questions regarding the return of this product please contact Qualanex at 1-888-504- 2014 (live calls received 7:00 am to 4:00 pm M-F CST).

Consumers with questions regarding this recall can contact Vi-Jon, LLC by e-mail (Recalls@Vijon.com) Monday-Friday, from 7:30 am to 4:30 pm, Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.www.vijon.com