DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

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

10/24/2022

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.

Aurobindo Pharma USA, Inc. began shipping of the subject batches, QE2021005-A and QE2021010-A to customers nationwide May 2021.

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.

Quinapril and Hydrochlorothiazide Tablets USP 20 mg / 12.5 mg are "Pink colored, scored, round shaped, biconvex, film-coated tablets, debossed with 'D' on scored side and '19'on other side", supplied in 90's HDPE bottle.

The product label is as shown below:

Qualanex, on behalf of Aurobindo Pharma USA, Inc., will be notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Aurobindo Pharma USA, Inc. is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

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). Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

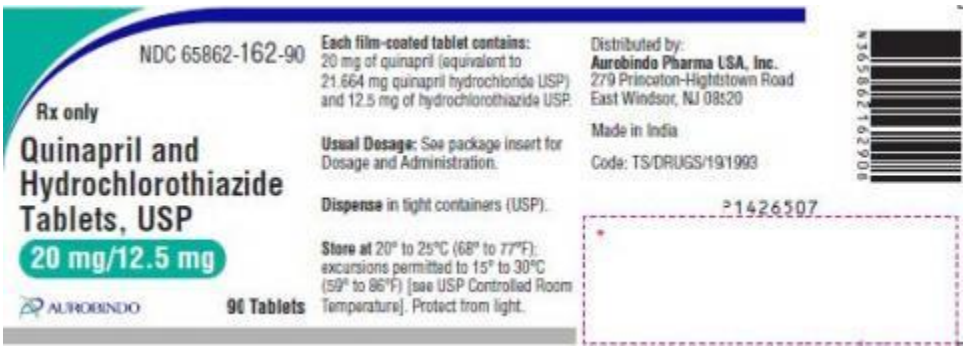
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Aurobindo Pharma USA, Inc.
1-866-850-2876
pvg@aurobindousa.com

Product Photos

- 

Source:https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-recall-two-2-lots-quinapril-and?utm_medium=email&utm_source=govdelivery