COMMUNICATION

COM-2022-058

01 NOVEMBER 2022

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

10.25.2022

Drug Information:

National Drug Code

65862-162-90

Product Description

QUINAPRIL AND HYDROCHLOROTHIAIZDE TABLETS USP 20MG-12.5MG

Lot Numbers

QE2021005-A, QE2021010-A

Expiration Date

JANUARY 2023

Company:

AUROBINDO PHARMA USA, INC

QUESTIONS

Call AUROBINDO PHARMA USA, INC. for medical questions at 1.866.850.2876 (option 2), 24 hours per day, 7 days per week.

Email AUROBINDO PHARMA USA, INC. at pvg@aurobindousa.com

Call QUALANEX for general questions regarding the return of this product at 1.888.504.2014 (live calls received Monday to Friday 7am to 4pm CST).

Quinapril and Hydrochlorothiazide

It is for this reason that we are notifying you that on 10.25.2022 the US Food and Drug Administration published a drug recall for the following product(s): Quinapril and hydrochlorothiazide tablets USP 20mg-12.5mg.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Aurobindo Pharma USA, Inc. has initiated a voluntary recall of two lots of quinapril and hydrochlorothiazide tablets USP 20mg-12.5mg to the consumer level due to the presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril above the proposed interim limit.

Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if individuals are exposed to them above acceptable levels over long periods of time. To date, Aurobindo Pharma USA, Inc. has not received any report of adverse events related to this recall.

Aurobindo Pharma USA, Inc. began shipping the subject batches to consumers nationwide May 2021.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2022-058 November 2022

pharmpix
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). 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. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-recall-two-2-lots-quinapril-and
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda