COMMUNICATION

COM-2022-018

04
APRIL
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 you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

03/22/2022

Drug Information:

National Drug Code

Refer to table in this notification for product details.

Product Description

Refer to table in this notification for product details.

Lot Number

Refer to table in this notification for product details.

Expiration Date

Refer to table in this notification for product details.

Company:

Pfizer

QUESTIONS

Call **Pfizer Medical Information** at 800-438-1985, option 3 for medical questions regarding the product

Call **Pfizer Drug Safety** at 800-438-1985, option 1 to report adverse events and product complaints

Monday – Friday from 8:00 a.m. to 9:00 p.m. ET.

Accuretic™, Quinapril and Hydrochlorothiazide and Quinapril HCl/hydrochlorothiazide Tablets

It is for this reason that we are notifying you that on 03/22/2022 the US Food and Drug Administration published a drug recall for the following product(s): Accuretic™ (quinapril HCl/hydrochlorothiazide); quinapril and hydrochlorothiazide; and quinapril HCl/hydrochlorothiazide.

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:

Pfizer is voluntarily recalling six lots of Accuretic™, one lot of Quinapril and hydrochlorothiazide tablets and four lots of quinapril HCl/hydrochlorothiazide tablets (brand product distributed by Pfizer and authorized generics distributed by Greenstone) to the consumer level. The reason for the recall is due to the presence of a nitrosamine, N-nitroso-quinapril, above the Acceptable Daily Intake (ADI) level. The presence of nitrosamines may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

To date, Pfizer is not aware of reports of adverse events that have been assessed to be related to this recall. Pfizer believes the benefit/risk profile of products remains positive based on currently available data.

The NDC, lot number, expiration date and strength details of the products that were recalled are indicated in the table below. The product lots were distributed nationwide to wholesalers and distributors in the United States and Puerto Rico from November 2019 to March 2022.

NDC	Lot Number	Expiration Date	Strength
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets			
0071-3112-23	FG5379	08/2024	10/12.5 mg
0071-0222-23	EA6686	04/2022	10/12.5 mg
0071-5212-23	FG5381	08/2024	20/12.5 mg
0071-0220-23	EA6665	04/2022	20/12.5 mg
0071-0220-23	CN0640	04/2022	20/12.5 mg
0071-0223-23	ET6974	02/2023	20/25 mg
Quinapril and hydrochlorothiazide tablets and quinapril HCl/hydrochlorothiazide tablets			
59762-5225-9	FE3714	02/2023	20/25 mg
59762-0220-1	DN6931	03/2023	20/12.5 mg
59762-0220-1	ED3904	03/2023	20/12.5 mg
59762-0220-1	ED3905	03/2023	20/12.5 mg
59762-0223-1	DP3414	02/2023	20/25 mg

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 COM-2022-018 April 2022

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Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). Pfizer Voluntary Nationwide Recall of Lots of Accuretic (Quinapril HCl/Hydrochlorothiazide), Quinapril and Hydrochlorothiazide Tablets, and Quinapril HCl/hydrochlorothiaizide Tablets Due to N-Nitroso-Quinapril Content. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuretictm-quinapril-hclhydrochlorothiazide-quinapril-and
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda