Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-038-CG
March 23, 2022

FDA announced that, Pfizer is voluntarily recalling Accuretic (quinapril HCl/hydrochlorothiazide) tablets distributed by Pfizer as well as two authorized generics distributed by Greenstone (quinapril and hydrochlorothiazide and quinapril HCl/ hydrochlorothiazide) to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-quinapril, above the Acceptable Daily Intake (ADI) level. Pfizer will recall six lots of Accuretic tablets, one lot of quinapril and hydrochlorothiazide tablets and four lots of quinapril HCl/ hydrochlorothiazide tablets.

RECOMMENDATIONS

1. Wholesalers and distributors with an existing inventory of the lots, should stop use, distribution and quarantine the product immediately.

2. Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the affected product. Patients with the affected product should contact Sedgwick at 888-843-0247 (Mon.-Fri. 8:00 am - 5:00 pm ET) for instructions on how to return their product and obtain reimbursement for their cost.

3. Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.- Fri. 8 am-9 pm ET)	For medical questions regarding the product
Pfizer Drug Safety	800 -438-1985External Link Disclaimer External Link Disclaimeroption 1 External Link Disclaimer	To report adverse events and product complaints

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Call Box 4908, Caguas, PR 00726

FDA U.S. FOOD & DRUG ADMINISTRATION

Pfizer Voluntary Nationwide Recall of Lots of ACCURETICTM (Quinapril HCl/Hydrochlorothiazide), Quinapril and Hydrochlorothiazide Tablets, and Quinapril HCl/Hydrochlorothiazide Tablets Due to N-NitrosoQuinapril Content

Summary:

Company Announcement Date:	**March 22, 2022**
FDA Publish Date:	**March 22, 2022**
Product Type:	**Drugs**
Reason for Announcement:	**Presence of a nitrosamine, N-nitroso-quinapril**
Company Name:	**Pfizer**
Brand Name:	**Accuretic, Greenstone Brand**
Product Description:	**Accuretic™ (quinapril HCl/hydrochlorothiazide); quinapril and hydrochlorothiazide; and quinapril HCl/hydrochlorothiazide tablets**

Company Announcement

NEW YORK, NY., March 21,2022. Pfizer is voluntarily recalling Accuretic (quinapril HCl/hydrochlorothiazide) tablets distributed by Pfizer as well as two authorized generics distributed by Greenstone (quinapril and hydrochlorothiazide and quinapril HCl/ hydrochlorothiazide) to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-quinapril, above the Acceptable Daily Intake (ADI) level. Pfizer will recall six lots of Accuretic tablets, one lot of quinapril and hydrochlorothiazide tablets and four lots of quinapril HCl/ hydrochlorothiazide tablets.

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.[i]

These products are indicated for the treatment of hypertension. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.*i* The products have a safety profile that has been established over 20 years of marketing authorization and through a robust clinical program. 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

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profile of the products remains positive based on currently available data. Although long term ingestion of N-nitroso-quinapril may be associated with a potential increased cancer risk in humans, there is no immediate risk to patients taking this medication. Patients currently taking the products should consult with their doctor about alternative treatment options.

The NDC, Lot Number, Expiration Date, and Configuration details for these products are indicated in the tables below and photos of the products can be found at the end of this press release. The product lots were distributed nationwide to wholesalers and Distributors in the United States and Puerto Rico from November 2019 to March 2022.

Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 10/12.5 mg
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/12.5 mg
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/25 mg

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0071-3112-23	FG5379	08/2024	10/12.5 mg	1 x 90 count bottle
0071-0222-23	EA6686	04/2022	10/12.5 mg	1 x 90 count bottle
0071-5212-23	FG5381	08/2024	20/12.5 mg	1 x 90 count bottle
0071-0220-23	EA6665	04/2022	20/12.5 mg	1 x 90 count bottle
0071-0220-23	CN0640	04/2022	20/12.5 mg	1 x 90 count bottle
0071-0223-23	ET6974	02/2023	20/25 mg	1 x 90 count bottle

quinapril and hydrochlorothiazide tablets, 20/25 mg
quinapril HCl/hydrochlorothiazide tablets, 20/12.5 mg
quinapril HCl/hydrochlorothiazide tablets, 20/25 mg

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-5225-9	FE3714	02/2023	20/25 mg	1 x 90 count bottle
59762-0220-1	DN6931	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0220-1	ED3904	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0220-1	ED3905	03/2023	20/12.5 mg	1 x 90 count bottle

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NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-0223-1	DP3414	02/2023	20/25 mg	1 x 90 count bottle

Pfizer places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Pfizer has notified direct consignees by letter to arrange for return of any recalled product.

Wholesalers and distributors with an existing inventory of the lots, listed in the table above, should stop use and distribution and quarantine the product immediately.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution of the affected product and promptly contact Sedgwick at 888-843-0247 (Mon.-Fri. 8:00 am - 5:00 pm ET) to obtain a Business Reply Card (BRC) to initiate the return process.

Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the affected product. Patients with the affected product should contact Sedgwick at 888-843-0247 (Mon.-Fri. 8:00 am - 5:00 pm ET) for instructions on how to return their product and obtain reimbursement for their cost.

Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

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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.

Call Box 4908, Caguas, PR 00726

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- Complete and submit the report Online
- Regular Mail or Fax: Download form 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

References:

i *https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications*

ii *William B, et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension. Eur Heart J 2018;39:3021-3104.doi:10.1093/eurheartj/ehy339.*