DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Pfizer Voluntary Nationwide Recall of Lots of ACCUPRIL® (Quinapril HCl) Due to N-Nitroso-Quinapril Content

4/22/2022

Pfizer is voluntarily recalling five (5) lots of Accupril (Quinapril HCl) tablets distributed by Pfizer to the patient (consumer/user) level due to the presence of a nitrosamine, Nnitroso-quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level.

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*

Accupril is indicated for the treatment of hypertension, to lower blood pressure. Accupril is also indicated in the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis. Accupril has a safety profile that has been established over 30 years. 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 the products remains positive based on currently available data. Although long-term ingestion of Nnitroso-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 or health care provider about alternative treatment options for them.

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 December 2019 to April 2022.

Accupril® (Quinapril HCl Tablets), 10 mg
Accupril® (Quinapril HCl Tablets), 20 mg
Accupril® (Quinapril HCl Tablets), 40 mg

NDC	Lot Number	Expiration Date	Strength	Configuration/ Count
0071-0530-23	DR9639	2023 MAR 31	10 mg	1 x 90 count bottle
0071-0532-23	DX8682	2023 MAR 31	20 mg	1 x 90 count bottle
	DG1188	2022 MAY 31	20 mg	1 x 90 count bottle
0071-0535-23	DX6031	2023 MAR 31	40 mg	1 x 90 count bottle
	CK6260	2022 MAY 31	40 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 888-345-0481 (Mon.-Fri. 8:00 am - 5:00 pm ET) to obtain a Business Reply Form (BRF) to initiate the return process.

If you received free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), please check your stock immediately against the table above. If you have any of the affected product lots in your inventory, please follow the instructions above for returning the product to Sedgwick. Additionally, if you are aware of any patients to whom you dispensed the affected lots who still may have the product in their possession, please ask them to return the product to you and then follow the instructions above for returning the product to Sedgwick. To request replacement product for any Pfizer PAP or Pfizer IPAP product you return, please contact 833-203-2776 (Mon.-Fri. 8 am-6 pm ET).

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 888-345-0481 (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.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.- Fri. 8 am-9 pm ET) www.pfizermedinfo.comExternal Link Disclaimer	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a	To report adverse events and product

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
- 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

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

References:

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

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Company Contact Information

Consumers:

Sedgwick

888-345-0481

Media:

+1 (212) 733-7410

PfizerMediaRelations@pfizer.com

Product Photos

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Source:https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuprilr-quinapril-hcl-due-n-nitroso-quinapril-content?utm_medium=email&utm_source=govdelivery