Accupril® (quinapril HCl) Tablets Recall Alert

Date of Notice: April 22, 2022

Brief Description of Recall Alert

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.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Accupril® (Quinapril HCl Tablets), 10 mg	0071-0530-23	DR9639	March 31, 2023
Accupril® (Quinapril HCl Tablets), 20 mg	0071-0532-23	DX8682	March 31, 2023
Accupril® (Quinapril HCl Tablets), 20 mg	0071-0532-23	DG1188	May 31, 2022
Accupril® (Quinapril HCl Tablets), 40 mg	0071-0535-23	DX6031	March 31, 2023
Accupril® (Quinapril HCl Tablets), 40 mg	0071-0535-23	CK6260	May 31, 2022

Prescriber Information

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.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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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.com	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	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

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members 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.

RxAdvance Response

Members should continue taking Accupril® until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.

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