Pfizer's Voluntary Nationwide Recall of Accuretic™ (Quinapril HCl/ Hydrochlorothiazide [HCTZ]) and Quinapril HCl/HCTZ Tablets Due to N-Nitroso-Quinapril Content

Date: 03/22/2022

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Pfizer has posted a lot recall of	Accuretic (quinapril hydrochloride [HCl]/HCTZ) tablets, 10/12.5 mg Accuretic (quinapril HCl/HCTZ) tablets, 20/12.5 mg Accuretic (quinapril HCl/HCTZ) tablets, 20/25 mg quinapril HCl/HCTZ tablets, 20/12.5 mg quinapril HCl/HCTZ tablets, 20/25 mg

About this recall:
Pfizer is voluntarily recalling Accuretic (quinapril HCl/hydrochlorothiazide) tablets distributed by Pfizer as well as authorized generics distributed by Greenstone (quinapril HCl/HCTZ tablets) to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-quinapril, above the acceptable daily intake level. Pfizer has recalled six lots of Accuretic tablets and five lots of quinapril HCl/HCTZ tablets.

What this means to you:
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.

Accuretic and quinapril HCl/HCTZ are indicated for the treatment of high blood pressure. Lowering blood pressure reduces the risk of cardiovascular events, primarily strokes and heart attacks. To date, Pfizer is not aware of reports of adverse events that have been assessed to be related to this recall. 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 NDCs, lot numbers, and expiration dates for the recalled products are provided in the FDA Recall Notification, linked on the following page. Photos of the products are also available at the FDA Recall Notification.

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 recalled product should contact Sedgwick at 888-843-0247 (Monday through Friday 8:00 am to 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)	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985 option 1	To report adverse events and product complaints

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

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuretic-quinapril-hclhydrochlorothiazide-quinapril-and

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.