

Pfizer – Recall of Accuretic[™] (quinapril/hydrochlorothiazide [HCTZ]), quinapril and HCTZ, and quinapril HCI/HCTZ

- On March 21, 2022, <u>Pfizer announced</u> a consumer-level recall of several lots of <u>Accuretic</u> (<u>quinapril/HCTZ</u>), <u>quinapril and HCTZ</u>, and quinapril HCl/HCTZ tablets due to the presence of a nitrosamine, N-nitroso-quinapril, above the Acceptable Daily Intake (ADI) level.
- The following products were distributed nationwide from November 2019 to March 2022.

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

- Brand and generic Accuretic tablets are indicated for the treatment of hypertension.
- 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 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.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the recalled brand or generic Accuretic tablets.
- 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 for instructions on how to return their product and obtain reimbursement
 for their cost.
- Contact Pfizer Medical Information at **1-800-438-1985**, **option 3** or Pfizer Drug Safety at **1-800-438-1985**, **option 1** for more information about the recall.



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