

## Pfizer – Recall of Accupril<sup>™</sup> (quinapril)

- On April 22, 2022, <u>Pfizer announced</u> a consumer-level recall of several lots of <u>Accupril (quinapril)</u> tablets due to the presence of a nitrosamine, N-nitroso-quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level.
- The following products were distributed nationwide from December 2019 to April 2022.

Product Description	NDC#	Lot# (Expiration Date)
Accupril (quinapril) 10 mg tablets	0071-0530-23	DR9639 (3/31/2023)
Accupril (quinapril) 20 mg tablets	0071-0532-23	DX8682 (3/31/2023); DG1188 (5/31/2022)
Accupril (quinapril) 40 mg tablets	0071-0535-23	DX6031 (3/31/2023); CK6260 (5/31/2022)

- Accupril is indicated for the treatment of hypertension and for the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis.
- 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 Accupril 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 888-345-0481 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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