# Accuretic™ (quinapril HCl/hydrochlorothiazide), quinapril and hydrochlorothiazide, quinapril HCl/hydrochlorothiazide tablets Recall Alert

Date of Notice: March 22, 2022

## Brief Description of Recall Alert

Pfizer is voluntarily recalling Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets as well as two (2) authorized generics distributed by Greenstone (quinapril and hydrochlorothiazide and quinapril HCl/ hydrochlorothiazide) due to the presence of a nitrosamine, N-nitroso-quinapril, above the acceptable daily intake level. Pfizer will recall six (6) lots of Accuretic™ tablets, one lot of quinapril and hydrochlorothiazide tablets, and four lots of quinapril HCl/ hydrochlorothiazide tablets.

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. 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.

## Affected Products

| Drug Name & Strength | NDC | Lot | Expiration Date |
|---|---|---|---|
| Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 10/12.5 mg | 0071-3112-23 | FG5379 | 08/2024 |
| | 0071-0222-23 | EA6686 | 04/2022 |
| Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/12.5 mg | 0071-5212-23 | FG5381 | 08/2024 |
| | 0071-0220-23 | EA6665 | 04/2022 |
| | | CN0640 | |
| Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/25 mg | 0071-0223-23 | ET6974 | 02/2023 |
| quinapril and hydrochlorothiazide tablets, 20/25 mg | 59762-5225-9 | FE3714 | 02/2023 |
| quinapril HCl/hydrochlorothiazide tablets, 20/12.5 mg | 59762-0220-1 | DN6931 | 03/2023 |
| | | ED3904 | |
| | | ED3905 | |
| quinapril HCl/hydrochlorothiazide tablets, 20/25 mg | 59762-0223-1 | DP3414 | 02/2023 |

## Prescriber Information

Pfizer has notified direct consignees by letter to arrange for return of any recalled product. Wholesalers and distributors with existing inventory of the lots, listed in the table above, should stop use and distribution, and quarantine the product immediately. 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.

Please contact Sedgwick at 888-843-0247 (Mon.-Fri. 8:00 am - 5:00 pm ET) to obtain a Business Reply Card to initiate the return process.

Healthcare professionals with questions regarding this recall can contact Pfizer using the below information:

- For medical questions regarding the product:
  - Pfizer Medical Information
  - 800-438-1985, option 3 (M-F, 8am-9pm ET)
- To report adverse events and product complaints:
  - Pfizer Drug Safety
  - 800-438-1985, option 1

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 with medical-related questions, who wish to report an adverse event or quality issues about the products being recalled, should contact Sedgwick at 888-843-0247 (Monday - Friday 8:00 am - 5:00 pm EST).

## RxAdvance Response

Members should continue taking their medication 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.