

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

**Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 10/12.5 mg**

**Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/12.5 mg**

**Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/25 mg**

| <b>NDC</b>   | <b>Lot Number</b> | <b>Expiration Date</b> | <b>Strength</b> | <b>Configuration/<br/>Count</b> |
|--------------|-------------------|------------------------|-----------------|---------------------------------|
| 0071-3112-23 | FG5379            | 08/2024                | 10/12.5 mg      | 1 x 90 count bottle             |
| 0071-0222-23 | EA6686            | 04/2022                | 10/12 .5 mg     | 1 x 90 count bottle             |
| 0071-5212-23 | FG5381            | 08/2024                | 20/12.5 mg      | 1 x 90 count bottle             |
| 0071-0220-23 | EA6665            | 04/2022                | 20/12.5 mg      | 1 x 90 count bottle             |
| 0071-0220-23 | CN0640            | 04/2022                | 20/12 .5 mg     | 1 x 90 count bottle             |
| 0071-0223-23 | ET6974            | 02/2023                | 20/25 mg        | 1 x 90 count bottle             |

**quinapril and hydrochlorothiazide tablets, 20/25 mg**

**quinapril HCl/hydrochlorothiazide tablets, 20/12.5 mg**

**quinapril HCl/hydrochlorothiazide tablets, 20/25 mg**

| <b>NDC</b>   | <b>Lot Number</b> | <b>Expiration Date</b> | <b>Strength</b> | <b>Configuration/<br/>Count</b> |
|--------------|-------------------|------------------------|-----------------|---------------------------------|
| 59762-5225-9 | FE3714            | 02/2023                | 20/ 25 mg       | 1 x 90 count bottle             |
| 59762-0220-1 | DN6931            | 03/2023                | 20/12.5 mg      | 1 x 90 count bottle             |
| 59762-0220-1 | ED3904            | 03/2023                | 20/12.5 mg      | 1 x 90 count bottle             |
| 59762-0220-1 | ED3905            | 03/2023                | 20/12.5 mg      | 1 x 90 count bottle             |
| 59762-0223-1 | DP3414            | 02/2023                | 20/25 mg        | 1 x 90 count bottle             |

Pfizer Inc. is recalling the above referenced lots of **Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, quinapril and hydrochlorothiazide tablets, and quinapril HCl/hydrochlorothiazide tablets.**

Pfizer initiated this recall due to the presence of n-nitroso-quinapril above the Acceptable Daily Intake (ADI) level. Pfizer conducted a toxicological evaluation to establish an ADI, which incorporated numerous conservative assumptions. Pfizer also conducted a Product Assessment, including an evaluation of safety surveillance data. Based on Pfizer's assessments, the benefit/risk of quinapril and hydrochlorothiazide remains positive based on currently available data. Although a potential excess lifetime cancer risk from n-nitroso-quinapril may exist, it is considered to be low based on currently available data.

The recall of the above referenced lots of **Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, quinapril and hydrochlorothiazide tablets, and quinapril HCl/hydrochlorothiazide tablets** is being conducted to the **Consumer/User level**.