Drug recall notice for quinapril products

To assist you in the care of your patients, we would like to alert you to the recall of some quinapril products, effective October 2022.[1,2] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall. We have listed alternative options below.

The U.S. Food and Drug Administration (FDA) announced that recent testing showed results of a nitrosamine drug substance-related impurity, N-nitroso-quinapril, above the acceptable daily intake level.[1,2] The N-nitroso-quinapril impurity has been classified as a probable human carcinogen by the International Agency for Research on Cancer. The FDA contacted several companies recommending they voluntarily recall their products. Assessments are underway to determine whether quinapril product recalls will result in shortages, and the FDA will work closely with manufacturers to prevent or reduce any impact of shortages.

To date, the manufacturers have received no reports of adverse events related to this recall.

Medications included in this recall

Product name	NDC number	Lot number	Expiration date
Quinapril and hydrochlorothiazide 20 mg/12.5 mg tablets, 90-count bottle[1]	65862-0162-90	QE2021005-A	01/2023
		QE2021010-A	01/2023
Quinapril 20 mg tablets[2]	68180-0558-09	G102929	04/2023
Quinapril 40 mg tablets[2]	68180-0554-09	G100533 G100534 G203071	12/2022 12/2022 03/2024

Recommendations

To reduce impact to your patients, please consider the following alternative options:

Medication	Preferred alternatives
Quinapril and hydrochlorothiazide	Lisinopril and hydrochlorothiazide
Quinapril	Lisinopril

To access CarePlus' formulary drug list search, go to www.careplushealthplans.com/medicare-plans/2023-prescription-drug-guides.

Information for providers:[1,2]

- We have sent a letter to your CarePlus-covered patients who have had a claim for quinapril products and asked them to contact their physicians or healthcare providers if their medication is included in the recall and if they have experienced problems that may be related to using these drug products.
- Patients may report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by regular mail or by fax.
    - **Online:** Complete and submit the report.
        - Select "Consumer/Patient (FDA Form 3500B)."
    - **Regular mail or fax:** Download the form.
        - Complete and submit "Form FDA 3500B – Voluntary Reporting for Consumers" by mail to the address on the form or by fax to (332-0178).

References:

1. "Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Recall of Two (2) Lots of Quinapril and Hydrochlorothiazide Tablets USP 20mg/12.5mg, Due to the Detection of N-Nitroso Quinapril Impurity," U.S. Food and Drug Administration, last accessed Jan. 3, 2023, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-recall-two-2-lots-quinapril-and.
2. "Lupin Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Four Lots of Quinapril Tablets Due to Potential Presence of N-Nitroso-Quinapril Impurity," U.S. Food and Drug Administration, last accessed Jan. 3, 2023, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-four-lots-quinapril-tablets-due.