Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-094-CG
December 22, 2022

FDA announced that: Lupin Pharmaceuticals Inc. is voluntarily recalling four (4) lots of Quinapril Tablets to the patient (consumer/user) level due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level. To date, Lupin has received no reports of illness that appear to relate to this issue.

RECOMMENDATIONS

1. Lupin Pharmaceuticals Inc. is notifying its wholesalers, distributors, drug chains, mail order pharmacies and supermarkets by phone and through recall notification and is arranging for the return of all the recalled product lots.

2. Patients taking, Quinapril Tablets USP, 20mg, and 40mg are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.

3. Wholesalers, distributors and retailers that have Quinapril Tablets USP, 20mg, and 40mg that are being recalled should discontinue distribution of the recalled product lots immediately.

4. Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at **(877) 538-8445 Monday – Friday 09:00 am to 05:00 pm EST**. For reimbursement, please have the recalled lots returned to Inmar Rx Solutions, Inc.; the lot number can be found on the side of the bottle label.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

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FDA U.S. FOOD & DRUG ADMINISTRATION

Lupin Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Four Lots of Quinapril Tablets Due to Potential Presence of N-Nitroso-Quinapril Impurity

Summary:

Company Announcement Date:	December 21, 2022
FDA Publish Date:	December 21, 2022
Product Type:	Drugs
Reason for Announcement:	Presence of nitrosamine impurity, N-Nitroso-Quinapril
Company Name:	Lupin Pharmaceuticals Inc.
Brand Name:	Lupin
Product Description:	Quinapril 20 and 40 mg tablets

Company Announcement

Baltimore, Maryland, December 21, 2022: Lupin Pharmaceuticals Inc. is voluntarily recalling four (4) lots of Quinapril Tablets to the patient (consumer/user) level due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level. To date, Lupin has received no reports of illness that appear to relate to this issue.

Lupin discontinued the marketing of Quinapril tablets in September 2022.

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.

Quinapril tablet USP is an angiotensin-converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Quinapril Tablets USP 20mg, and 40mg is packaged in 90 count bottles and was distributed nationwide in the US to wholesalers, drug chains, mail order pharmacies and supermarkets. The recalled lots are included in the table below:

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Product	Lot No	Expiry	NDC	UPC	Distribution Dates
Quinapril Tablets USP, 20mg	G102929	04/2023	68180-558-09 (90's)	368180558095	03/15/2021 – 09/01/2022
Quinapril Tablets USP, 40mg	G100533 G100534 G203071	12/2022 12/2022 03/2024	68180-554-09 (90's)	368180554097	

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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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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**
- https://www.fda.gov/safety/report-problem-fda

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