Lupin PharmaceuticalsIssues Voluntary Nationwide Recall of 4 Lots of Quinapril Tablets USP, 20 mg and 40 mg Due to Potential Presence of N-Nitroso-Quinapril Impurity

Date: 12/21/2022

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Lupin Pharmaceuticals has posted a 4 lot recall of Quinapril Tablets USP, 20 mg and 40 mg.

About this recall:
Lupin Pharmaceuticals is voluntarily recalling 4 lots of Quinapril Tablets USP, 20 mg and 40 mg 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.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found below.

Quinapril tablet USP is an angiotensin-converting enzyme (ACE) inhibitor indicated for the treatment of high 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:

Quinapril Tablets USP, 40mg	**G100533** **G100534** **G203071**	**12/2022** **12/2022** **03/2024**	**68180-554-09** **(90's)**	**368180554097**

What this means to you:

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.

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.

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.

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.

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.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-four-lots-quinapril-tablets-due

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.