



Clifton Health Department Food Recall Notification



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Food/Drug/Pet Recall: Lupin Pharmaceuticals, Inc.

Lupin Pharmaceuticals Inc. is voluntarily recalling Metformin Hydrochloride Extended-Release Tablets USP (generic equivalent of Fortamet®), 500mg, lot G901203 to the consumer level. FDA analysis revealed that this lot exceeded the Acceptable Daily Intake Limit for the impurity N-Nitrosodimethylamine (NDMA).

To date, Lupin Pharmaceuticals Inc. has not received any reports of adverse events related to this recall.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products and vegetables.

Metformin Hydrochloride Extended-Release Tablets USP, 500mg is a prescription oral medication indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. It is packaged in a bottle containing 60 tablets with NDC 68180-336-07. The affected lot of Metformin Hydrochloride Extended-Release Tablets USP, 500mg is included in below table:

Product Name	NDC	Lot Number	Expiration Date
Metformin Hydrochloride Extended-Release Tablets USP, 500mg	68180-336-07	G901203	12/2020

The product can be identified by the NDC and the lot number available on the side of the bottle label. Metformin Hydrochloride Extended-Release Tablets USP, 500mg was distributed nationwide in the USA to wholesalers, distributors, and mail order pharmacies.

Lupin Pharmaceuticals Inc. is notifying its wholesalers, distributors, and mail order pharmacies by phone and through recall notification and is arranging for the return of all the recalled product lot. Patients taking Metformin Hydrochloride Extended-Release Tablets, USP 500 mg, are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. According to the U.S. Food & Drug Administration, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. Please visit the agency's website for more information at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin>.

Wholesalers, distributors, and retailers that have Metformin Hydrochloride Extended-Release Tablets USP, 500mg which is being recalled should discontinue distribution of the recalled product lot immediately and return it to Inmar Rx Solutions, Inc., 635 Vine St, Winston Salem, NC 27101. Tel: (855) 532-1856.



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Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at (855) 532-1856 Monday - Friday 09:00 am to 05:00 pm EST. For reimbursement, please have the recalled lot returned to Inmar Rx Solutions, Inc.: the lot number can be found on the side of the bottle.

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 U.S. Food and Drug Administration.

No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from either FDA or USDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

For all recalls - <http://www.recalls.gov/recent.html>