Lupin Pharmaceuticals Issues Voluntarily Nationwide Recall of Metformin ER Tablets, 500 mg and 1,000 mg Due to the Detection of NDMA Impurity

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Lupin Pharmaceuticals is voluntarily recalling all batches of Metformin Hydrochloride (HCl) Extended-Release (ER) Tablets USP, 500 mg and 1000 mg to the consumer level. As part of the ongoing assessment and continuation of dialog with the Food & Drug Administration (FDA), additional analysis revealed that certain tested batches were above the acceptable daily intake (ADI) limit for the impurity N-Nitrosodimethylamine (NDMA). Out of an abundance of caution, the company is recalling all batches of Metformin HCl ER Tablets USP, 500 mg and 1,000 mg in the United States (US). To date, Lupin Pharmaceuticals 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 is found in water and foods, including meats, dairy products, and vegetables.

Metformin ER 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. Metformin ER tablets 500 mg and 1,000 mg are packaged in 60, 90, and 100 count bottles and were distributed nationwide in the US to wholesalers, distributors, drug chain pharmacies, mail order pharmacies, and supermarkets. The recalled NDCs are included in the table below:

Product	Strengths	NDC	Distribution Dates
Metformin HCl ER Tablets, USP	500 mg	68180-0338-01	11/21/2018 - 05/27/2020
	1,000 mg	68180-0339-09	
	500 mg	68180-0336-07	11/05/2018 - 05/22/2020
	1,000 mg	68180-0337-07	

Lupin Pharmaceuticals is notifying its wholesalers, distributors, drug chain pharmacies, mail order pharmacies, and supermarket customers by phone and through recall notification and is arranging for the return of all the recalled product NDCs.

Patients taking Metformin HCl ER Tablets, USP 500 mg or 1,000 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 US FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare 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 HCl ER Tablets USP, 500 mg and 1,000 mg that are being recalled should discontinue distribution of the recalled product NDCs immediately and return it to Inmar Rx Solutions, 635 Vine St., Winston Salem, NC 27101 (phone 855-532-1856).

Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at (855) 532-1856 Monday through Friday 9:00 AM to 5:00 PM EST. For reimbursement, please have the recalled NDCs returned to Inmar Rx Solutions; the NDC number can be found on the top 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 US FDA.

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-metformin-hydrochloride-extended.

Company Contact Information

Consumers:

Inmar, Rx Solutions, Inc.
(855) 532-1856

Media:

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Product Photos

Click here for product photos.