

Lupin Issues Voluntary Nationwide Recall of Metformin ER Tablets, 500 mg, Due to the Detection of NDMA

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Lupin Pharmaceuticals Inc. is voluntarily recalling Metformin Hydrochloride Extended-Release (ER) Tablets USP (generic equivalent of Fortamet®), 500 mg, lot G901203, to the consumer level. FDA analysis revealed that this lot exceeded the Acceptable Daily Intake (ADI) limit for the impurity N-Nitrosodimethylamine (NDMA). To date, Lupin 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 (such as 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. The product is packaged in a bottle containing 60 tablets with NDC 68180-0336-07. The impacted lot of metformin ER tablets 500 mg is listed in the below table:

Product Name	NDC	Lot Number	Expiration Date
Metformin Hydrochloride Extended-Release Tablets USP, 500mg	68180-0336-07	G901203	12/2020

The product can be identified by the NDC and lot number listed on the side of the bottle label. Metformin ER tablets were distributed nationwide in the United States (US) to wholesalers, distributors, and mail order pharmacies.

Lupin is notifying these wholesalers, distributors, and mail order pharmacies by phone and through recall notification and is arranging for the return of all the recalled product. The manufacturer is advising patients taking recalled product to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. According to the US Food & Drug Administration (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 ER 500 mg tablets which are being recalled should discontinue distribution of the recalled product lot 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 lot returned to Inmar Rx Solutions; 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 US Food and Drug Administration.

Company Contact Information

Consumers:

Inmar Rx Solutions, Inc.

(855) 532-1856

Media:

Arvind Bothra

+91-22-66402137

arvindbothra@lupin.com

Product Photos

For product photos, please refer to the FDA Link: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-one-lot-metformin-hydrochloride>