

Recall of Metformin ER Tablets, 500 mg and 1,000 mg, by Lupin Pharmaceuticals

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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 market recall of metformin extended-release (ER) tablets, 500 mg and 1,000 mg.

About this Recall:

Lupin Pharmaceuticals is voluntarily recalling all batches of Metformin ER Tablets, 500 mg and 1,000 mg to the consumer level. As part of the ongoing evaluation and communication with the Food & Drug Administration (FDA), additional testing showed 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 ER tablets in the strengths of 500 mg and 1,000 mg in the United States (US).

What this means to you:

NDMA is 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 tablets are a prescription oral medication used as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. The recalled NDCs are available at the FDA Recall Notification link found in the box on the following page.

Patients taking recalled metformin ER tablets, 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 providers. 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>.

Consumers with questions regarding this recall should contact Inmar Rx Solutions 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.

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-voluntarily-nationwide-recall-metformin-hydrochloride-extended>

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 select prompt #2.