Metformin ER 500 mg Tablets

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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 recall of Metformin Extended-Release (ER) Tablets, 500 mg.

About this Recall:
Lupin Pharmaceuticals is voluntarily recalling 1 lot of Metformin ER Tablets, 500 mg, to the consumer level.

FDA testing showed that this lot had higher levels than the Acceptable Daily Intake limit for the impurity N-Nitrosodimethylamine (NDMA).

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 (such as meats, dairy products, and vegetables).

The FDA Recall Notification linked below lists the recalled NDC and lot number. 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.

Patients with recalled metformin ER tablets are advised by the manufacturer 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 provider.

Consumers with questions about 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 lot returned to Inmar Rx Solutions; the lot number can be found on the side of the bottle.

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-one-lot-metformin-hydrochloride

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.