Viona Pharmaceuticals Issues Voluntary Nationwide Recall of Metformin HCl Extended-Release Tablets, 750 mg, Due to the Detection of NDMA Impurity

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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.

Viona Pharmaceuticals has posted a lot recall of Metformin HCl Extended-Release Tablets, USP 750 mg.

About this recall:
Viona is voluntarily recalling 2 lots of metformin hydrochloride (HCl) extended-release (ER) tablets, USP 750 mg to the retail level. The 2 lots of metformin HCl ER tablets, 750 mg have been found to contain levels of N-Nitrosodimethylamine (NDMA) above acceptable daily limits. This product was manufactured by Cadila Healthcare in November 2019 for United States (US) distribution by Viona.

What this means to you:
NDMA is classified as a substance that could cause cancer based on results from laboratory tests. NDMA is an environmental contaminant, found in water and foods (including meats, dairy products, and vegetables). **Patients who have received recalled lots of metformin HCl ER tablets 750 mg are advised to continue taking their medication and contact their physician for advice regarding an alternative treatment.** According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professionals (HCPs). To date, neither Viona, nor Cadila Healthcare have received any reports of adverse events related to this recall.

Metformin is used as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus and is packaged in plastic bottles of 100 tablets, under NDC 72578-036-01. The recalled lots (batches) of metformin HCl ER tablets 750 mg are listed at the link in the box on the following page. The product can be identified as white to off-white, capsule shaped, uncoated tablets, debossed with "Z", "C" on one side and "20" on the other side.

Consumers with questions regarding this recall can contact the recall processor Eversana Life Science Services by phone at 1-888-304-5022, option 1; Monday to Friday, 8:00 am – 7:00 pm CDT. Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking or using this drug product.

Customers with medical-related questions, who wish to report an adverse event, or quality issues about the recalled products should contact Viona by phone at 888-304-5011, Monday to Friday, 8:30 am – 5:30 pm EST.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets

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 selecting prompt #2.