Viona Issues Voluntary Nationwide Recall of Metformin HCl Extended-Release Tablets, USP 750 mg, Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

Date: 01/12/2022

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 Hydrochloride (HCl) Extended-Release (ER) Tablets.

About this recall:
Viona is voluntarily recalling twenty-three (23) lots of Metformin HCl ER Tablets, USP 750 mg at the consumer level due to the detection of the NDMA impurity. The reason for the recall is an out of specification result found for one (1) lot of the product's long-term stability samples. In an abundance of caution, the firm has decided to voluntarily recall 23 batches which they have determined having a valid shelf life within the United States (US) market. This product was manufactured by Cadila Healthcare Limited, India for US distribution by Viona Pharmaceuticals.

What this means to you:
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. **Patients who have received impacted lots of Metformin HCl ER Tablets, USP 750mg 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). 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. To date, neither Viona nor Cadila have received any reports of adverse events related to this recall.

The product 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 72578-0036-01. **The recalled lots of Metformin HCl ER Tablets, USP 750 mg are listed at the link 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. The tablets were distributed nationwide to distributors.

Consumers with questions regarding this recall can contact the recall processor, Inmar Pharmaceutical Services, by phone at 1-855-249-3303, option 1; Monday through Friday (excluding holidays), 9 am to 5 pm, EST.

Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking or using this drug product.

Viona is notifying its customers by email and mail (FedEx Overnight) and is arranging for the return of all recalled products to our recall processor at the following address:

Inmar Pharmaceuticals Services-Recalls
3845 Grand Lakes Way,
Grand Prairie, Texas 75050

Customers with medical-related questions, who wish to report an adverse event, or quality issues about the products being recalled should contact Viona by phone at 888-304-5011, Monday through Friday, 8:30 am to 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-0

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.