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

FDA Publish Date: 01/12/2022

Viona is voluntarily recalling twenty-three (23) lots of Metformin Hydrochloride (HCl) Extended-Release (ER) Tablets, USP 750 mg at the consumer level. The reason for the recall is an out of specification result observed for one lot of the product (M008132) "NDMA (by GC- MS/MS)" test at 17 months, 25°C/60%RH 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, Ahmedabad, India for US distribution by Viona Pharmaceuticals Inc.

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 is found in water and foods, including meats, dairy products, and vegetables. **Patients who have received impacted lots of Metformin HCl ER Tablets, USP 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). 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 high-density polyethylene (plastic) bottles of 100 tablets, under NDC 72578-0036-01. **The recalled lots of Metformin HCl ER Tablets, USP 750 mg are listed in the table 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.

Product Name: Metformin HCl ER Tablets, USP 750 mg NDC: 72578-0036-01		
Sr. Number	Batch Number	Exp. Date
1.	M008130	06/2022
2.	M008131	06/2022
3.	M008132	06/2022
4.	M008133	06/2022
5.	M010080	07/2022
6.	M010081	07/2022
7.	M011029	08/2022
8.	M011030	08/2022
9.	M011031	08/2022
10.	M011032	08/2022
11.	M011304	08/2022
12.	M013394	09/2022
13.	M013395	09/2022
14.	M013396	09/2022
15.	M013966	09/2022
16.	M013967	09/2022
17.	M100831	12/2022
18.	M100832	12/2022
19.	M100833	01/2023
20.	M100834	01/2023
21.	M101267	01/2023
22.	M102718	01/2023
23.	M102719	01/2023

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.

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

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.

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0

Company Contact Information

Consumers:

Inmar Pharmaceutical Services
1-855-249-3303

Product Photos

Click here for product photos.