Important Drug Recall

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-009-CG
January 13, 2022

FDA announced that, **Viona Pharmaceuticals Inc.,** is voluntarily recalling **twenty-three (23)** lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** at the **consumer level.** The reason for the recall is an Out of Specification (OOS) result observed for one lot of the product (M008132) "N-nitrosodimethylamine (NDMA) (By GC-MS/MS)" test at 17 Month(s), 25°C/60%RH Long-term stability samples. In an abundance of caution, the firm has decided to voluntarily recall 23 batches which we have determined having a valid shelf life within the US market. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India for U.S. distribution by Viona Pharmaceuticals Inc.

RECOMMENDATIONS

1. **Viona Pharmaceuticals Inc.,** 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

2. Consumers with questions regarding this recall can contact our recall processor **Inmar Pharmaceutical Services by phone at 1-855-249-3303,** option 1; Monday – Friday (excluding holidays), 9:00 am – 5:00 pm, EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
3. Customers with medical-related questions, who wish to report an adverse event, or quality issues about the products being recalled should contact **Viona Pharmaceuticals Inc., by phone at: 888-304-5011,** Monday - Friday, 8:30 am – 5:30 pm, EST.
4. Review your inventory to identify existence of recalled products.
5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Call Box 4908, Caguas, PR 00726

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Summary:

Company Announcement Date:	January 07, 2022
FDA Publish Date:	January 12, 2022
Product Type:	Drugs
Reason for Announcement:	N-Nitrosodimethylamine (NDMA) Impurity
Company Name:	Viona Pharmaceuticals, Inc.
Brand Name:	Viona
Product Description:	Metformin Hydrochloride Extended-Release Tablets

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE – 01/07/2022 – Cranford, New Jersey, Viona Pharmaceuticals Inc., is voluntarily recalling **twenty-three (23)** lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** at the **consumer level.** The reason for the recall is an Out of Specification (OOS) result observed for one lot of the product (M008132) "N-nitrosodimethylamine (NDMA) (By GC- MS/MS)" test at 17 Month(s), 25°C/60%RH Long-term stability samples. In an abundance of caution, the firm has decided to voluntarily recall 23 batches which we have determined having a valid shelf life within the US market. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India for U.S. 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 found in water and foods, including meats, dairy products, and vegetables. Patients who have received impacted lots of Metformin Hydrochloride Extended-Release 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. 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

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Pharmaceuticals Inc., nor Cadila Healthcare Limited 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 **HDPE bottles of 100 tablets, under NDC 72578-036-01**. The recalled lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** are listed in the below table. 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. Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** was distributed **Nationwide** to **Distributors**.

Product Name: Metformin Hydrochloride Extended-Release Tablets, USP 750 mg **NDC:** 72578-036-01		
Sr. No.	**Batch No.**	**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

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Product Name: Metformin Hydrochloride Extended-Release Tablets, USP 750 mg **NDC:** 72578-036-01		
Sr. No.	**Batch No.**	**Exp. Date**
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

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

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**