COMPANY ANNOUNCEMENT

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:

June 11, 2021

FDA Publish Date:

June 11, 2021

Product Type:

Drugs

Reason for Announcement:

Contains Nitrosodimethylamine (NDMA) impurities

Company Name:

Viona Pharmaceuticals Inc.

Brand Name:

Viona Pharmaceuticals Inc.

Product Description:

Metformin Hydrochloride Extended-Release Tablets

Company Announcement

Viona Pharmaceuticals Inc., is voluntarily recalling **2 (two)** lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** to the retail level. The **2 (two)** lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** have been

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found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India in November 2019, 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 (/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin). To date, neither Viona 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 affected 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 Description	NDC No.	Batch No.	Exp. Date
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg	72578-036-01	M915601	Oct-2021
		M915602	Oct-2021

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

Eversana Life Science Services
c/o Viona recall
ATTN: Returns Department
4580 S. Mendenhall Rd.
Memphis, TN 38141

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Consumers with questions regarding this recall can contact our recall processor **Eversana Life Science Services by phone at 1-888-304-5022**, option 1; Monday – Friday, 8:00 am – 7:00 pm CDT. 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.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Eversana Life Science Services

1-888-304-5022, option 1

Product Photos

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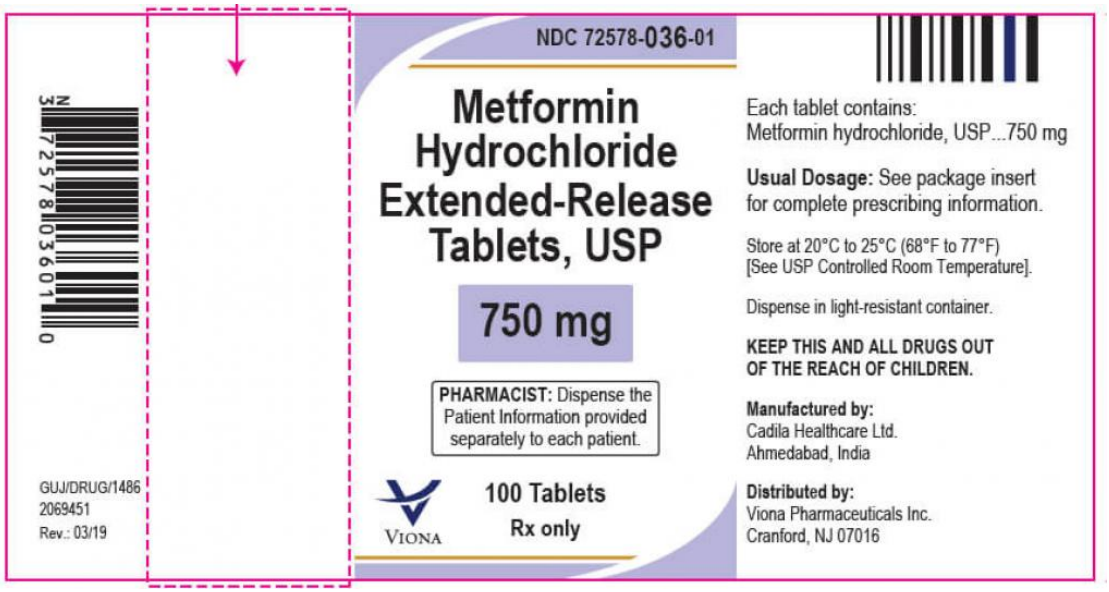

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)

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