



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**

Company Contact:

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FOR IMMEDIATE RELEASE – 12/28/2021 – Cranford, New Jersey, Viona Pharmaceuticals Inc., is voluntarily recalling **thirty three (33)** lots of **Metformin Hydrochloride Extended-Release Tablets, USP 750 mg** to the **retail level**. Reason for the recall is an Out of specification result observed for the said product, Lot number M008132, “N-nitrosodimethylamine (NDMA) (By GC-MS/MS)” test at 17 Month(s), 25°C/60%RH Long-term stability samples. As a precautionary measure firm voluntarily recall all the marketed 33 batches having valid shelf life. 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 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**. Firm recalled **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**.

Viona Pharmaceuticals Inc.

20 Commerce Drive, Ste 340, Cranford, NJ 07016

Phone: +1 908 956 0600 * Fax: +1 908 514 4005 * www.vionausa.com



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
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
24.	M102720	01/2023
25.	M102721	02/2023
26.	M102722	02/2023
27.	M104172	02/2023
28.	M104173	02/2023
29.	M104174	02/2023
30.	M104175	02/2023
31.	M104176	02/2023
32.	M105889	03/2023
33.	M105890	03/2023

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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

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**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.

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Product Label:

The image shows a rectangular product label for Metformin Hydrochloride Extended-Release Tablets, USP 750 mg. The label is divided into several sections. On the left side, there is a vertical barcode with the number 3 72578 103601 0 printed vertically next to it. Below the barcode, the text reads: GUJ/DRUG/1486, 2069451, Rev.: 03/19. The top right corner features the NDC number 72578-036-01 and a standard barcode. The main body of the label contains the product name in large, bold letters: Metformin Hydrochloride Extended-Release Tablets, USP. Below this, the strength 750 mg is displayed in a purple box. A box for the pharmacist contains the instruction: PHARMACIST: Dispense the Patient Information provided separately to each patient. At the bottom left of the main section, the Viona logo is shown next to the text 100 Tablets Rx only. On the right side, there are several paragraphs of text: Each tablet contains: Metformin hydrochloride, USP...750 mg; Usual Dosage: See package insert for complete prescribing information; Storage instructions: Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]; Dispense in light-resistant container; A warning: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.; Manufacturer information: Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India; and Distributor information: Distributed by: Viona Pharmaceuticals Inc. Cranford, NJ 07016. A pink dashed line outlines the entire label, and a pink arrow points down from the top edge of this line.

NDC 72578-036-01

3 72578 103601 0

GUJ/DRUG/1486
2069451
Rev.: 03/19

**Metformin
Hydrochloride
Extended-Release
Tablets, USP**

750 mg

PHARMACIST: Dispense the
Patient Information provided
separately to each patient.

**100 Tablets
Rx only**

Each tablet contains:
Metformin hydrochloride, USP...750 mg

Usual Dosage: See package insert
for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].

Dispense in light-resistant container.

**KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Distributed by:
Viona Pharmaceuticals Inc.
Cranford, NJ 07016

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