Metformin 750mg

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 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**.

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.
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.