Viona – Recall of metformin

- On January 7, 2022, Viona announced a consumer level recall of twenty-three lots of metformin 750 mg tablets due to the detection of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake limit in one lot.

- The recalled lots were distributed between August 2020 and December 2021.

Product Description	NDC	Lot # (Expiration Date)
Metformin 750 mg extended-release tablets	72578-036-01	M008130 (6/2022)
		M008131 (6/2022)
		M008132 (6/2022)
		M008133 (6/2022)
		M010080 (7/2022)
		M010081 (7/2022)
		M011029 (8/2022)
		M011030 (8/2022)
		M011031 (8/2022)
		M011032 (8/2022)
		M011304 (8/2022)
		M013394 (9/2022)
		M013395 (9/2022)
		M013396 (9/2022)
		M013966 (9/2022)
		M013967 (9/2022)
		M100831 (12/2022)
		M100832 (12/2022)
		M100833 (1/2023)
		MI00834 (1/2023)
		M101267 (1/2023)
		M102718 (1/2023)
		M102719 (1/2023)

- Metformin is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.

- If patients have the recalled metformin, they should continue taking it and contact their pharmacy for a safe replacement. There are other companies that make metformin ER tablets that are not being recalled and a new prescription may not be needed.

- According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals.

- Patients who have the recalled metformin ER should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled metformin ER.

Continued . . .

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Viona at **1-888-304-5011** for more information about the recall. Contact Inmar by phone at **1-855-249-3303** or by email at **RXrecalls@inmar.com** for return information.
- NDMA and cancer risk:
    - NDMA is classified as a probable human carcinogen. It is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
    - The FDA does not know how long patients may have been exposed to higher NDMA levels in ER metformin.
    - The FDA does not expect nitrosamines to cause harm when ingested at or below the acceptable intake limit levels (such low levels of nitrosamines are present in foods in low levels and ingested as part of usual diets) even over a long period of time (such as a 70-year lifespan).
    - Nitrosamine impurities may increase the risk of cancer if people are exposed to them at above acceptable levels over long periods of time, but the FDA does not anticipate that shorter term exposure at levels above the acceptable intake limit would lead to an increase in the risk of cancer.
- See here for more information from the FDA about metformin products and NDMA contamination.

optumrx.com