



Nostrum Laboratories – Recall of metformin extended-release (ER)

- On November 2, 2020, Nostrum announced a voluntary, consumer level recall of some lots of [metformin 500 mg ER](#) and [750 mg ER](#) tablets due to contamination with n-nitrosodimethylamine (NDMA) above the acceptable daily intake (ADI) limit of 96 ng/day.
- The recalled metformin tablets were distributed nationwide to wholesalers.

Product Description	NDC#	Lot# (Expiration Date)
Metformin 500 mg ER tablets	29033-055-01	MET100201 (05/2022); MET100401 (05/2022)
Metformin 750 mg ER tablets	29033-056-01	MET200101 (05/2022); MET200301 (05/2022)

- 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.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Nostrum Laboratories by phone at **1-816-308-4941** or by email at **quality@nostrumpharma.com** for further information regarding this recall.
- 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

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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.



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