

Nostrum Issues Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 500 mg and 750 mg, Due to NDMA Content Above the Acceptable Daily Intake Limit

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Nostrum Laboratories has posted a lot recall of metformin.

About this Recall:

Nostrum Laboratories is recalling 2 lots of Metformin Hydrochloride (HCl) Extended Release (ER) Tablets, USP 500 mg and 2 lots of Metformin HCl ER Tablets, USP 750 mg. These products are being recalled as they contain levels of nitrosamine impurities above the Acceptable Daily Intake (ADI) limit of 96 ng/day.

What this means to you:

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 is found in water and foods (including meats, dairy products, and vegetables). Nostrum has not received any reports of adverse events related to this recall.

Metformin HCl ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Product is packaged in HDPE bottles of 100 tablets, with NDC 29033-055-01 (500 mg) or NDC 29033-056-01 (750 mg). The 500 mg product can be identified as an off-white oblong tablet debossed with "NM5", and the 750 mg product can be identified as an off-white oblong tablet debossed with "NM7". The impacted lots of Metformin HCl ER Tablets, USP 500 mg and 750 mg can be found at the FDA Recall Notification links on the following page.

Consumers should consult a healthcare professional (HCP) to obtain a replacement or a different treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their HCP. Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking this drug product.

Consumers with medical questions regarding this recall can contact Nostrum Medical Affairs at phone number 816-308-4941 or via email at quality@nostrumpharma.com Monday through Friday from 8 am to 5 pm CST. Consumers should contact their physician or pharmacy for further medical advice.

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](#).
- Regular Mail or Fax: [Download form](#) 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 United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website:

500 mg: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0>

750 mg: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets>

FDA contact information for reporting adverse events/quality complaints can be reached online at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.