

FDA Recall of Metformin ER Tablets, 750 mg by Granules Pharmaceuticals

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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.

Granules Pharmaceuticals has posted a lot recall of metformin extended-release (ER) tablets, 750 mg.

About this recall:

Granules Pharmaceuticals is voluntarily recalling twelve (12) lots of Metformin ER Tablets, 750 mg, supplied in 100 and 500 count bottles within expiration to the consumer level due to the detection of N-Nitrosodimethylamine (NDMA) levels above the acceptable daily intake (ADI) limit.

Granules' test results showed NDMA levels above the FDA's acceptable limit in one (1) out of the twelve (12) batches distributed in the United States (US). All other batches continue to remain within the required limits. Out of abundance of caution, Granules Pharmaceuticals has decided to voluntarily recall all twelve (12) of the distributed lots within expiration of metformin ER tablets, 750 mg.

Granules' metformin immediate-release (IR) tablets in the strengths of 500 mg, 850 mg, and 1,000 mg as well as their metformin ER tablets in the 500 mg strength are not impacted by this recall.

What this means to you:

NDMA is 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).

Metformin ER tablets, 750 mg, are used as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus. Details for identifying the recalled lots are available at the FDA Recall Notification link found on the following page.

Patients with questions regarding this recall or wishing to return product may contact Inmar Pharmaceutical Services recall processor for instructions and a return kit for returning their medication:

- Contact Inmar at 888-985-9117 (hours of operation: 9 AM to 5 PM Eastern Time, Monday through Friday) or email Inmar at: rxrecalls@inmar.com
- Inmar will provide the materials needed to return medication and instructions for reimbursement

If you would like to report any adverse reactions or quality problems experienced with the use of this product you may contact Granules Drug Safety by phone at 1-877-770-3183 Monday through Friday, 8:00 AM to 8:00 PM EST, or via email at drugs.safety@granulesindia.com.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/granules-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended>

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.