

Metformin ER 500 mg Tablets

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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.

Amneal has posted a recall of Metformin Hydrochloride Extended-Release (ER) Tablets, 500 mg and 750 mg.

About this Recall:

Amneal Pharmaceuticals is voluntarily recalling all lots of Metformin ER Tablets, 500 mg and 750 mg, within expiry to the retail level.

Amneal was notified by the United States (US) Food and Drug Administration (FDA) that the agency's testing of seven lots of Metformin ER Tablets, 500 mg and 750 mg, showed N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels. FDA recommended the recall of the seven tested lots. Amneal has agreed to this recall and has further decided to extend the recall to all lots within expiry of Metformin Hydrochloride ER Tablets, 500 mg and 750 mg, to be extra careful.

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 (such as meats, dairy products, and vegetables). The impacted metformin ER tablets can be identified by the NDC number found on the product label. The recalled NDC number is listed on the FDA Recall Notification at the link below. The FDA has stated patients should continue taking metformin tablets, even after recalls occur, until they speak with their healthcare provider who can prescribe a replacement.

Amneal is notifying its direct customers via mail (UPS Standard Overnight) by mailing a recall notification letter and is arranging for return of all the recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers who purchased the impacted product directly from Amneal may call Amneal at 1-833-582-0812 or email to AmnealproductrecallDS@amneal.com, Monday – Friday, 8:00 am – 5:00 pm, EST, for further information.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended?utm_campaign=Metformin%20%20N-Nitrosodimethylamine%20%28NDMA%29%20by%20Amneal&utm_medium=email&utm_source=Eloqua

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.

