

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.

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

About this Recall:

Apotex is voluntarily recalling all lots of Metformin Hydrochloride (HCl) ER Tablets, 500 mg within expiration to the retail level. The United States (US) Food and Drug Administration (FDA) tested 1 lot of Apotex's metformin HCl ER tablets, and found that tablets contain levels of the N-Nitrosodimethylamine (NDMA) impurity greater than the acceptable daily intake limit. As a result, the FDA recommended recall of the 1 tested lot. Apotex is recalling this lot, and out of an abundance of caution, the company has extended the recall to include all lots of Apotex's metformin ER tablets in the US. Selling of this product was stopped in the US in February 2019 and only limited product remains on the market. To date, there have not been any reports of adverse events related to use of this product.

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.

Consumers with questions regarding this recall can contact Apotex by phone at 1-800-706-5575 (8:30 AM – 5:00 PM, EST Monday through Friday) or email UScustomerservice@Apotex.com. Consumers should contact their physician or health-care provider if they have experienced any problems that may be related to taking or using this drug product.

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