

# Apotex Issues Voluntary Nationwide Recall of Metformin ER Tablets, 500 mg Due to the Detection of NDMA

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Apotex Corp. is voluntarily recalling all lots of Metformin Hydrochloride (HCl) ER Tablets, USP 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 it was found to 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 HCl 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, no reports of adverse events related to use of this product have been received.

**Risk Statement:** NDMA is classified as 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 FDA has stated patients should continue taking metformin tablets, even after recalls occur, until they speak with their health care provider who can prescribe a replacement.

Metformin HCl ER tablet is a prescription oral product indicated as an adjunct to diet and exercise to improve blood sugar control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. The impacted metformin HCl ER tablets can be identified by NDC number found on the product label.

Product	Strength	Pack Size	NDC Number
Metformin Hydrochloride Extended-Release Tablets, USP	500 mg	100's bottle	60505-0260-01

The impacted metformin ER tablets were distributed nationwide in the US to warehouse chains. Apotex is in the process of notifying its affected direct account wholesaler, distributor, chain distribution, and warehousing chains via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product.

Wholesalers, distributors and retailers should return the recalled product to the place of purchase. Anyone with an existing inventory of the product should quarantine the recalled lots immediately. Customers who purchased the impacted product directly from Apotex can call Inmar Rx Solutions at 1-888-985-9014 (option 1) (9:00 AM – 5:00 PM, EST Monday through Friday), to arrange for their return.

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](mailto:UScustomerservice@Apotex.com). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 US Food and Drug Administration (FDA).

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## Company Contact Information

### Consumers:

Apotex Corp.

1-800-706-5575

[UScustomerservice@Apotex.com](mailto:UScustomerservice@Apotex.com)

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## Product Photos

