

COMPANY ANNOUNCEMENT

Apotex Corp. Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets 500mg Due to the Detection of N-nitrosodimethylamine (NDMA)

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

May 27, 2020

FDA Publish Date:

May 28, 2020

Product Type:

Drugs

Reason for Announcement:

Due to detection of N-Nitrosodimethylamine (NDMA)

Company Name:

Apotex Corp

Brand Name:

Apotex Corp

Product Description:

Metformin Hydrochloride Extended-Release Tablets, USP 500mg

Company Announcement

Apotex Corp is voluntarily recalling all lots of Metformin Hydrochloride Extended-Release Tablets, USP 500mg within expiry to retail level. Apotex was notified by the U.S. Food and Drug Administration (US FDA) that one lot of Metformin Hydrochloride Extended-Release Tablets, USP was tested and showed results for N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI) and recommended recall of the one tested lot. Apotex Corp

has agreed to recall this lot, and out of an abundance of caution, the company is extending the recall to all lots of Metformin Hydrochloride Extended-Release Tablets in the US. Apotex stopped selling this product in the US in February 2019, and there remains only limited product on the market. To date, Apotex has not received any reports of adverse events related to use of the product.

Risk Statement: 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 found in water and foods, including meats, dairy products, and vegetables.

Metformin Hydrochloride Extended-Release Tablets, USP 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 affected Metformin Hydrochloride Extended-Release Tablets, USP can be identified by NDC numbers stated on the product label.

Product	Strength	Pack Size	NDC Number
Metformin Hydrochloride Extended-Release Tablets, USP	500mg	100's Bottle	60505-0260-1

The affected Metformin Hydrochloride Extended-Release Tablets were distributed nationwide in the USA to Warehousing Chains. Apotex Corp. is in a 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) (9:00am – 5:00-pm, EST Monday thru Friday), to arrange for their return.**

Consumers with questions regarding this recall can contact Apotex Corp. by phone at 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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 U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Apotex Corp.

☎ 1-800-706-5575

✉ UScustomerservice@Apotex.com (mailto:UScustomerservice@Apotex.com)

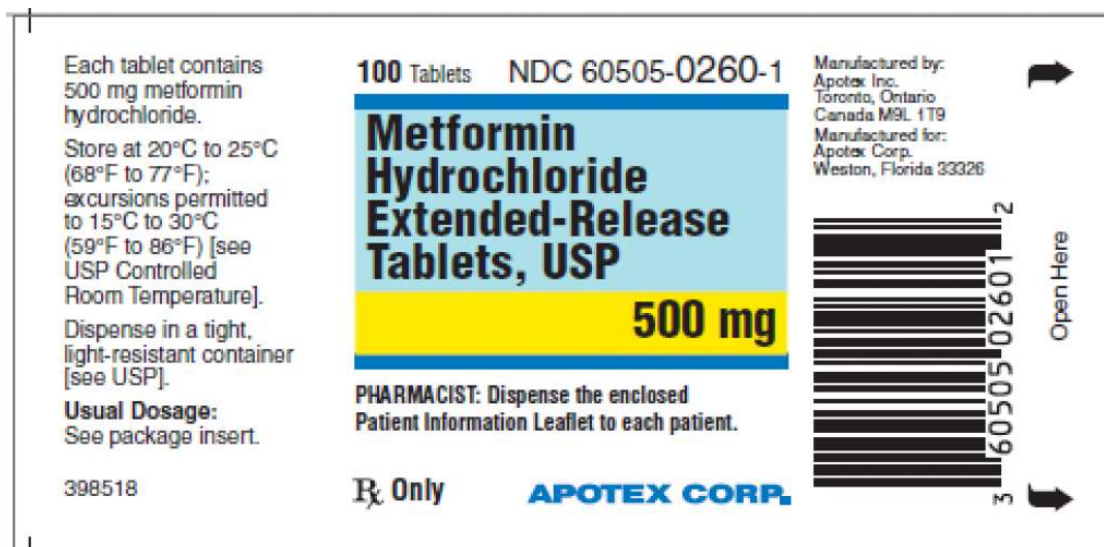
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Product Photos



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