Metformin Hydrochloride Extended Release Tablets – Apotex Pharmaceuticals

On May 27, 2020, the U.S. Food and Drug Administration (FDA) announced that Apotex Pharmaceuticals, Inc. is voluntarily recalling Metformin Hydrochloride Extended-Release Tablets, 500mg.

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.

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.

Patients who have received impacted lots of Metformin Hydrochloride Extended-Release Tablets, USP 500mg or have questions regarding this recall please contact your pharmacy. Individuals should not interrupt their therapy, contact their health care provider for medical advice and should return the impacted product to their pharmacist.

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**
Metformin Hydrochloride Extended-Release Tablets	500mg	100’s Bottle	60505-0260-1

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).