RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 05/27/2020

Brief Description of Recall Alert

On May 27, 2020, Apotex Corp. voluntarily recalled all lots of metformin hydrochloride extended release 500mg tablets. Apotex Corp. was notified by the U.S. Food and Drug Administration (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.

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.

Drug Name & Strength	NDC	Lot	Expiration Date
metformin hydrochloride extended-release tablets, USP 500 MG	60505-0260-1	All lots	All dates

Prescriber Information

To date, Apotex Corp. has not received any reports of adverse events related to use of the 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

Member Information

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.

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.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise those impacted by this recall.